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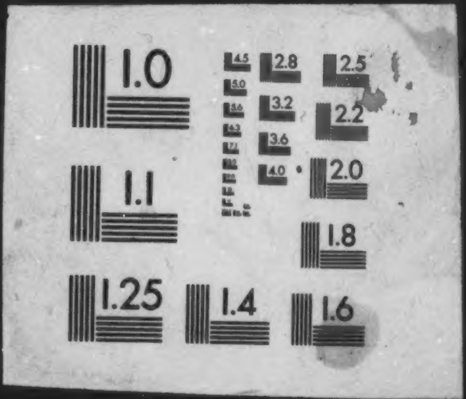
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Chemical Substances Designation
Volume 3: Other Federal Agencies

ICF, Inc.
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Prepared for

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This volume, part of a four volume study, examines EPA and other Federal agencies statutory and regulatory criteria for the designation of chemical substances. Volume I, a comparative analysis of the statutory authorities described in Volumes II and III, focuses on statutory purposes and goals, integration directives, the risks to be regulated, and the factors considered for designating and regulating chemical substances. The designation of chemical substances for regulation, hazard classifications and testing requirements are compared in the last section of Volume I. Volumes II and III review statutory provisions and regulations relating to the EPA and other Federal agency designation of chemical substances. The reviews focus on the criteria used to designate chemicals for regulation (e.g. role of economic and technological factors). The reviews specify which chemical substances are designated for regulation and each volume describe and analyze the hazard classification systems established and corresponding test methods required by the regulations. Volume IV, the chemical designation matrix provides a listing of the substances designated by regulation under the statues reviewed as they appear in the Code of Federal Regulations or the Federal Register (for proposed rules) as of January 1981.

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CHEMICAL SUBSTANCES DESIGNATION

VOLUME 3:

OTHER FEDERAL AGENCIES

Project Officer:

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December 1981

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DISCLAIMER

The information included in this report include regulations or policies that were proposed or promulgated as of January 1, 1981 by the U.S. Environmental Protection Agency and other federal agencies. Because the regulations and policies described are subject to differing interpretations and their status may have changed since January 1, 1981, the reader is cautioned to view the materials in this light. In addition, this report is not intended to be a comprehensive up-to-date listing of all regulations or policies, but rather should be used to retrospectively understand how agencies designate chemical substances. The contents of this report were prepared under contract to EPA and, though reviewed by EPA and other agency staff, this review does not necessarily reflect the views and policies of the U.S. Environmental Protection Agency nor those of the other federal agencies whose authorities and regulations are reviewed.

Foreword

A major factor that contributes to integration of EPA as well as interagency activities on chemicals is understanding the purposes and major objectives that must be considered by each statute when designating chemicals for regulation. Because of the numerous statutes and regulations with differing purposes that designate hazardous materials, wastes or substances and toxic pollutants or substances, confusion often results.

The purpose of this four volume study is to lay out the key factors required by the statutes and their implementing regulations that must be considered when designating chemicals. The document serves as a ready reference to those faced with designing as well as complying with federal regulatory actions regarding chemicals.

Walter W. Kovalick, Jr.

Walter W. Kovalick, Jr.
Director
Integration Staff

PREFACE

Chemical Substances Designation is a four volume report, of which this is Volume 3. An Index to the entire series follows the Table of Contents for Volume 1. This volume complements Volume 2's review of EPA authority by covering the following agencies:

(1) Occupational Safety and Health Administration
(2) Department of Transportation
(3) Food and Drug Administration
(4) United States Department of Agriculture
(5) Consumer Product Safety Commission
(6) Nuclear Regulatory Commission

For each agency, the statute or statutes authorizing chemical substances designation are examined. The statutory reviews cover the statutory provisions, legislative history, court cases and settlements that are relevant to each agency's authority to designate hazardous chemicals. The regulatory reviews focus on the regulations promulgated under each statute, and, more specifically, the criteria used to designate chemicals or products for regulation, and the substances regulated.

The statutory and regulatory reviews are analyzed in Volume 1 and the chemicals designated are included in the matrix comprising Volume 4.

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OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

The Occupational Safety and Health Administration (OSHA) is responsible for the implementation of the Occupational Safety and Health Act of 1970. The legal reviews and analyses that follow do not necessarily represent the official position of OSHA or the Department of Labor. Moreover, this material has not been officially endorsed by the EPA as its understanding of OSHA authority over toxic materials. The contractor, ICF Incorporated, is solely responsible for all analyses and interpretations. The material includes statutory and regulatory events through February 15, 1981 only.

OCCUPATIONAL SAFETY AND HEALTH ACT -- STATUTORY REVIEW

INTRODUCTION

The Occupational Safety and Health Act (OSH Act) became law on December 29, 1970.[1] One purpose of the OSH Act is to authorize enforcement of occupational safety and health standards "to assure safe and healthful working conditions for working men and women."[2]

An occupational safety and health standard as defined by the OSH Act is "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment.[3] There is no definition of toxic or hazardous substances included in the OSH Act.

Three sections of the OSH Act authorize OSHA to promulgate occupational safety and health standards to control toxic and hazardous substances.

(1) Section 6(a) required OSHA to quickly promulgate as health standards existing national consensus standards and established Federal standards.[4]

(2) Section 6(b) expressly authorizes OSHA to "promulgate, modify or revoke any occupational safety or health standard" if the Agency determines that a rule should be issued in order to serve the "objectives" of the Act.

---

[1] Pub. L. 91-596, 29 U.S.C. § 651 et seq.

[2] OSH Act Section 1, 29 U.S.C. § 651.

[3] OSH Act Section 3(8), 29 U.S.C. § 652.

[4] "The term 'national consensus standard' means any occupational safety and health standard or modification thereof which (1) has been adopted and promulgated by a nationally recognized standards-producing organization under procedures whereby it can be determined by the Secretary that persons interested and affected by the scope or provisions of the standard have reached substantial agreement on its adoption, (2) was formulated in a manner which afforded an opportunity for diverse views to be considered and (3) has been designated as such a standard by the Secretary, after consultation with other appropriate Federal agencies." (OSH Act Section 3(9))

"The term 'established Federal standard' means any operative occupational safety and health standard established by any agency of the United States and presently in effect, or contained in any Act of Congress in force on the date of enactment of this Act." (OSH Act Section 3(10))

(3) Section 6(c) authorizes OSHA to establish an emergency temporary standard to protect employees from "grave danger" resulting from exposure to "toxic or physically harmful" substances.

Section 6(a). In accordance with Section 6(a) of the OSH Act, OSHA promulgated an initial standards package on May 29, 1971 which incorporated existing federal safety and health standards as well as national consensus standards. The incorporated federal standards were primarily those standards originally contained in the Walsh-Healy Public Contracts Act.[5] The national consensus standards adopted by OSHA were issued previously either by the American National Standards Institute or by the National Fire Protection Association (36 FR 10466); ANSI Standards were issued primarily to deal with product liability; NFPA for fire prevention (i.e., property protection), worker safety and health were secondary considerations.

The initial standards package designated about 400 chemical substances as air contaminants and adopted threshold limit values (from the national consensus standards) as exposure standards for them. See 29 CFR 1910.1000.

Section 6(b). OSHA has designated for regulation twenty-three toxic and hazardous substances under Section 6(b). The statutory criteria for determining which chemicals are designated for regulation are the "objectives" of the Act. These objectives include: "To assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources."

Section 6(b) directs OSHA to express the standards "in terms of objective criteria and of the performance desired". Standards developed under Section 6(b) may include provisions for permissible exposure limits, action levels,[6] labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and medical examinations at no cost to employees. In addition, Section 8(c) of the OSH Act permits standards to prescribe recordkeeping requirements where "necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational accidents and illnesses

---

[5] The Walsh-Healy Public Contracts Act of June 30, 1936 prohibits hazardous or dangerous working conditions for employees engaged in the performance of contracts with the United States Government. Other federal standards incorporated into OSHA's standards package include operative occupational safety and health standards in effect on April 28, 1971, and established by the Department of Labor pursuant to Section 107 of the Contract Work Hours and Safety Standards Act, as amended (40 U.S.C. § 333); Section 41 of the Longshoremen's and Harbor Workers' Compensation Act, as amended (33 U.S.C. § 941); the Service Contract Act of 1965 (41 U.S.C. § 351); or pursuant to the National Foundation on the Arts and Humanities Act (20 U.S.C. § 951).

[6] An action level triggers monitoring and medical surveillance requirements prior to exceeding the permissible exposure limit.

The substantive requirements for health standards are specified in Section 6(b)(5) where the level of protection that standards must provide is ex- plained. As Section 6(b)(5) states, OSHA, "in promulgating standards dealing with toxic materials . . ., shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life" (emphasis added).

This statutory provision also stipulates the factors OSHA must consider when developing health standards. These factors are:

- "the attainment of the highest degree of health and safety protection for the employee"
- "the best available evidence"
- "research, demonstrations, experiments, and such other information as may be appropriate"
- "the latest available scientific data in the field"
- "the feasibility of the standards," and
- "experience gained under this and other health and safety laws."

The legislative history of the OSH Act clarifies the meaning of "the best available evidence". It urges OSHA not to allow the standard setting process to be "paralyzed by debate surrounding diverse medical opinion."[7] Furthermore, the courts which have reviewed standards promulgated under the Act have supported this Congressional judgment. For example, the U.S. Court of Appeals for the Second Circuit in sustaining the standard for occupational exposure to vinyl chloride suggested that OSHA may develop health standards "even in circumstances where existing methodology or research is deficient."[8] The U.S. Court of Appeals for the District of Columbia applied a similar rationale in reviewing the asbestos standard. The Court stated that:

> Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision-making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.[9]

---

[7] House Committee on Education and Labor, Report No. 91-1291, 91st Congress, 2d Session, p. 18 (1970).

[8] Society of the Plastics Industry Inc. v. Occupational Safety and Health Administration, 509 F.2d 1301, 1308 (2nd Cir. 1975).

[9] Industrial Union Department, AFL-CIO v. Hodgson, 499 F.2d 467, 474 (D.C.Cir., 1974).

Judicial review of the health standards also has clarified the meaning of "feasibility" as a criterion for developing health standards. The asbestos standard decision confirmed OSHA's authority to consider economic and technological feasibility in setting standards.[10] The U.S. Court of Appeals for the Second Circuit (in reference to the vinyl chloride standard) decided that considerations of technological feasibility were not limited to exposure control devices already developed and in use. The Court asserted that standards could require improvements in existing technologies or require the development of new technology.[11] Feasibility is discussed in more detail below.

Section 6(c). Several 6(b) rulemaking proceedings establishing permanent health standards began with the development of emergency temporary standards under Section 6(c) (e.g., the asbestos standard). Emergency temporary standards take effect immediately upon publication in the Federal Register and are effective for 6 months or until superseded by a permanent standard or stayed judicially, whichever occurs first.[12] ETS's have not been extensively used by OSHA for controlling toxic substance exposures in the workplace.

CASELAW REVIEW

In the area of toxic substance regulation, OSHA workplace standards have been a significant source of litigation. Recently, the Supreme Court addressed OSHA's authority in this area and the kinds of risks it can regulate. Other cases have concerned the role of economic factors and the meaning of "feasibility".

Court review of OSHA standards has centered on three provisions of the OSH Act:

(1) Section 3(8)--Definition of an "occupational safety and health standard."

(2) Section 6(b)(5)--Requirements for promulgation of standards dealing with "toxic materials or harmful physical agents"; and,

(3) Section 6(f)--The review process for a challenged OSHA standard.

The Supreme Court's benzene decision will be reviewed in conjunction with the discussion of Section 3(8). The different holdings of the Justices will be reviewed as summarized in Exhibit 1-1. Other key cases will be discussed as appropriate. These cases are summarized in Exhibit 1-2.

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[10] Industrial Union Department v. Hodgson, No. 72-1713 (April 15, 1973).

[11] Society of the Plastics Industry, Inc. v. OSHA, supra at 1309.

[12] Cases concerning emergency temporary standards have not been included in this review.

EXHIBIT 1-1

OVERVIEW OF SUPREME COURT HOLDINGS IN ITS BENZENE DECISION

Holding	Justice
- The benzene regulation is invalid because OSHA didn't first make a finding that a "significant risk" existed.	Stevens Burger Stewart Powell
- The benzene regulation is invalid because OSHA didn't show a "reasonable relationship" between its costs and benefits.	Powell
- The benzene regulation is invalid because Congress gave OSHA totally inadequate guidance on how to set a standard.	Rehnquist
- The benzene regulation is valid and OSHA is not required to find either a "significant risk" or a reasonable cost-benefit relationship.	Marshall Brennan White Blackmun
- OSHA may regulate risks that are not subject to quantification on the basis of the best available evidence.	Powell Marshall Brennan White Blackmun

EXHIBIT 2

SUMMARY OF KEY CASES CHALLENGING OSHA STANDARDS

Standard	Case	Date	Circuit	Summary of Decision
Asbestos	Industrial Union Department, AFL-CIO v. Hodgson	1974	D.C.	• A regulation, concerning a subject on the frontiers of scientific knowledge about which there is insufficient data for a fully informed factual decision, generally requires a policy decision by OSHA. • A court is entitled to a careful explanation of why OSHA reached a specific decision rather than some other decision. • Congress did not mean to protect employees by putting their employers out of business. • A standard that is "prohibitively expensive" is not feasible. • In general a standard can be feasible, even though it substantially increases production costs, adversely affects profit margins, or causes the "economic demise" of an employer who has dragged its feet in protecting the safety and health of its employees.
14 Carcinogens	Synthetic Organic Chemical Manufacturers Ass'n v. Brennan	1974	Third	• Where present knowledge is insufficient to determine a "safe" level of exposure to a substance, OSHA can rely on "respectable opinion" that such a level does exist. OSHA's decision in such an instance is a reasonable exercise of its policy judgment.
Vinyl Chloride	The Society of the Plastics Industry, Inc. v. OSHA	1975	Second	• When a safe exposure level cannot be identified, it is not erroneous for OSHA to set a PEL. The court implies that it is a matter for OSHA's discretion. • Technological feasibility entails engineering technology, work practices, and personal protective gear. • OSHA standards can be technology-forcing. OSHA is not limited to the status quo.
Mechanical Power Press	AFL-CIO v. Brennan	1975	Third	• Whenever the record is rich in statistical evidence, OSHA's decision based on that evidence will be subject to the substantial evidence test. • OSHA is not limited to considering technological feasibility only for regulations regarding toxic substances. • Technological feasibility includes existing technology and "imminent" technological advances. • This court adopted the pragmatic limits on economic feasibility set in Industrial Union. However, this court focused on economic infeasibility resulting in wide-spread evasion of the standard and the attendant enforcement difficulties.

EXHIBIT 2
(Continued)

SUMMARY OF KEY CASES CHALLENGING OSHA STANDARDS

Standard	Case	Date	Circuit	Summary of Decision
Coke Oven Emissions	American Iron and Steel Institute et al. v. OSHA	1978	Third	• If overwhelming scientific evidence is available, the substantial evidence test applies. • The setting of a PEL, from a technologically feasible standpoint, is a policy judgment not subject to the substantial evidence test. It must, however, be reasonably drawn from the record. • Technological feasibility may be tied to industry's past experience in reducing work exposure to workplace hazards. • The certainty of technological feasibility need not be absolute. • OSHA must balance the cost to industry against the health needs of workers, but does not have to quantify the benefits in dollar terms. • Massive economic dislocation is a benchmark of economic feasibility.
Benzene	American Petroleum Institute, et al. v. OSHA	1978	Fifth	• Any standard promulgated by OSHA must be reasonably necessary or appropriate to provide safe or healthful workplaces. • A toxic substance standard must be feasible, must use available, relevant information, and must be reasonably necessary to protect workers. • An elaborate cost-benefit analysis is not necessary, but costs and benefits must be estimated so a determination can be made whether a reasonable relation exists between them. This estimate must be supported by substantial evidence. • The requirement of substantial evidence is not satisfied by mere rationality. There must be measurable benefits. • A lack of information is no excuse for failure to make concrete estimates of benefits.

EXHIBIT 2
(Continued)

SUMMARY OF KEY CASES CHALLENGING OSHA STANDARDS

Standard	Case	Date	Circuit	Summary of Decision
Cotton Dust	AFL-CIO et al. v. Marshall	1979	D.C.	• Section 6(b)(5) is a mandate to reduce the risk of reversible damage. The prevalence of chronic byssinosis can be reduced by applying regulations that are stringent enough to reduce the occurrence of the reversible acute stage of byssinosis. • Technical feasibility must be "sufficiently supported ... with material in the record." OSHA's determination of feasibility was supported by (1) evidence in the record that much of the industry met or was close to meeting the PEL, (2) reliance on best available evidence, and (3) other circuits' decisions upholding technological feasibility where the Agency had less support than that here. • Reaffirm the economic feasibility standard applied in the challenge to the asbestos standard--some firms can be put out of business, but not an entire industry. • "Best available evidence" does not mean the Agency must await further study that will improve the record. • The OSH Act does not require a formal cost-benefit analysis. The OSH Act reflects Congress' own cost/benefit analysis re: workplace safety and health. Cite Section 6(b)(5) as support for conclusion that Congress determined the benefits of health protection justified the cost of an effective standard. -- Note that Court indicates cost/benefit might make OSHA's decisions worse by obscuring actual costs and benefits. • NOTE: This case has been appealed to the United States Supreme Court which has limited review to three questions: (1) should the Supreme Court resolve the conflict between the Circuits (D.C. v. 5th, 6th, and 7th) regarding what OSHA must show to demonstrate the feasibility of a proposed standard; (2) is the statutory requirement that a standard be "economically feasible" satisfied by the conclusion that the industry will not be put out of business; and (3) should the Supreme Court resolve the conflict between the D.C. and Fifth Circuits regarding whether the OSH Act requires a demonstration that a standard is reasonably necessary and that there is some reasonable relation between the standard's benefits and costs.

EXHIBIT 2
(Continued)

SUMMARY OF KEY CASES CHALLENGING OSHA STANDARDS

Standard	Case	Date	Circuit	Summary of Decision
Cotton Gin Dust	Texas Independent Ginners Ass'n, et al. v. Marshall	1980	Fifth	• OSHA failed to satisfy the threshold requirement that substance being regulated (cotton dust in cotton gins) posed a significant health risk. • OSHA failed to find that this standard was "reasonably necessary or appropriate" to protect workers. • NOTE: The Fifth Circuit set out a complicated review standard. Section 6(f), "substantial evidence" applies to both factual and policy determinations. In regard to factual determinations, the standard is satisfied when a finding is based on evidence of equivalent quality to the conflicting evidence. In regard to policy decisions, the standard is satisifed in a two-step process: (1) is the decision consistent with the statutory language and purpose--that is, (i) the action must be justified by a "significant risk of material impairment" to health, and (ii) the action must be both technologically and economically feasible; (2) is the decision "reasonable" in light of the state of the record--that is, (i) are there enough facts available and have they been investigated so that the policy judgment is "rational," (ii) are the factual premises underlying the policy judgment supported by substantial evidence, and (iii) is the policy judgment "reasonably related" to the substantial evidence.
Lead	United Steel Workers of America v. Marshall	1980	D.C.	• Medical removal protection is within OSHA's authority. • The standard satisfies the threshold "significant harm" requirement that the Supreme Court has required under Section 3(8). The Circuit Court differentiated the lead standard from the benzene standard by the less ambitious scope of the lead standard--it did not strive for a risk-free environment. • Feasibility does not require OSHA, at least in the pre-enforcement review period, to show absolute certainty every firm in the industry can meet the standard. • To demonstrate technological feasibility, OSHA must show that current technology has "conceived" of strategies or devices that are "likely" to be capable of meeting the PEL and that the industry will generally be capable of adopting. • To demonstrate economic feasibility, OSHA must "construct" a reasonable cost estimate and show that there is a "reasonable likelihood" such costs will not threaten the industry's viability.

EXHIBIT 2
(Continued)

SUMMARY OF PENDING CHALLENGES

Standard	Case	Filed	Circuit	Summary of Arguments
Arsenic	ASARCO, Inc., v. OSHA	1978	Ninth	• The industries argued that the requirement for economic feasibility had not been satisfied because (1) OSHA failed to complete the feasibility determination process; (2) the feasibility determination was not rational; and (3) the sole producer of arsenic would be forced out of business. -- OSHA claims the economic feasibility determination was complete and rational, and that the continued existance of a single employer is not necessary for economic feasibility. • Industry claimed the standard was not technologically feasible because engineering controls were insufficient to meet the PEL. -- OSHA replied that respirators combined with engineering controls made the standard technologically feasible. • Industry claimed that the standard was not necessary to protect workers. -- OSHA argued that the record supports its determination that the standard was necessary.

SECTION 3(8) AND THE SIGNIFICANT RISK TEST

Section 3(8) of the OSH Act has unexpectedly turned out to be a key provision. There is nothing in the legislative history to indicate that Congress considered it of any interest. Nevertheless, it is the basis for a major statement by the Supreme Court on OSHA's regulatory authority over toxic chemicals.

Section 3(8) defines a workplace standard as one requiring work practices or conditions which are:

> "Reasonably necessary or appropriate to provide safe or healthful employment and places of employment."

In the past, the Circuit Courts have interpreted Section 3(8) as giving OSHA considerable discretion in adopting protective workplace standards. For example, in the case of the cotton dust standard, industry argued that medical surveillance alone would protect against material impairment of health. The D.C. Circuit Court of Appeals, however, held that OSHA has the discretion to determine that only an exposure control strategy (e.g., control technology, work practices) is "reasonably necessary." Job transfer (i.e., rotation) has also been rejected by OSHA as a primary means of providing safe workplaces. Likewise, worker sterilization would not be considered by OSHA to be "reasonably necessary" or "appropriate."

However, Section 3(8) was interpreted in a very different fashion by the 5th Circuit Court of Appeals in its review of OSHA's benzene decision. Similarly the U.S. Supreme Court, hearing the benzene case on appeal, invalidated OSHA's benzene standard. While Section 3(8) was the ostensible basis of the decision, the Fifth Circuit's "reasonable relationship" cost-benefit test was not affirmed by the Supreme Court. Instead, a "significant risk"[13] threshold requirement was read from the phrase "reasonably necessary" in Section 3(8).

Although we review the derivation of the significant risk requirement in detail below, we first caution the reader that this case is a weak precedent. Five separate opinions were filed and a majority of Justices did not agree on a rationale for invalidating the standard (See Exhibit 1-1).

What does the phrase "reasonably necessary or appropriate" in Section 3(8) mean? OSHA argued that Section 3(8) imposes no substantive restriction because it is a merely definitional provision; thus, it allows any rational standard. Industry argued that, as held by the Fifth Circuit Court of

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[13] Note that the term "significant" refers to the probability of an adverse outcome, not the severity, nor the number of individuals affected. Section 6(b)(5) limits OSHA's authority to "material" impairments, in any case. Furthermore, the number of individuals affected is not germane because OSHA must be able to regulate hazardous chemicals encountered by only a limited number of workers (e.g., DBCP).

Appeals, "reasonably necessary" means that the standard's benefits must bear a reasonable relationship to its costs. The Supreme Court held that Section 3(8) requires OSHA to first find that a standard be "reasonably necessary and appropriate" to remedy a "significant risk" of material health impairment. This is termed a "threshold" finding because it must be satisfied before CSHA can proceed to develop a protective standard.

What is a significant risk? The Court explained that if the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk "clearly could not be considered significant." On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors containing two percent benzene will be fatal, the risk could reasonably be considered significant. The Court, however, leaves a wide gray zone between .001 and .000000001. Most toxic substances risks will probably fall right in this gray zone.[1a] This formulation suggests that agency regulations may be challenged as inadequate if they do not reduce the significant risk to a one in a billion chance of fatality. Moreover this approach works best for unidimensional health effects. It is not immediately clear how different types of health effects risks (e.g., cancer deaths, birth defects, chromosomal changes) are to be aggregated to determine if they constitute a significant risk. It is also unclear whether total exposures (including occupational exposures and exposures to other toxics in the environment) should be considered. There are thus several unanswered questions.

The phrase "significant risk" appears nowhere in the OSH Act. This threshold test was derived through the application of the following chain of logic:

(1) A standard must be reasonably necessary or appropriate for workplace safety and health (§ 3(8)).

(2) A standard can only be necessary or appropriate when there exists an unsafe or unhealthful workplace or the risk of one.

(3) "A workplace can hardly be considered 'unsafe' unless it threatens the workers with a significant risk of harm" (Justice Stevens).

(4) Therefore, a standard can only be necessary or appropriate when it can reduce a significant risk of harm.

[1a] For example, under the Clean Water Act, the EPA determines the quantities of hazardous polluting substances which may be harmful to the public health and environment if spilled into the waters. The EPA accomplishes this using a worst case scenario combined with a significance factor of a one in a million risk of fatal cancer. The Supreme Court's opinions may encourage some legal challenge to this methodology.

This reasoning, which has a certain abstract logic, may not, however, allow OSHA to establish a *margin of safety* for the protection of workers, in view of factors such as the scientific and factual uncertainties, unknown hazards, increased sensitivity of susceptible individuals and possible multiple exposures. OSHA might be prevented from applying *any* reasonable margin of safety to exposure limits if it is required to first demonstrate the existence of a significant risk; *arguing that an existing exposure standard provides an inadequate margin of safety (but not a significant risk) would probably not satisfy the significant risk requirement*.

The benzene case is complicated by the fact that there was a prior exposure standard (e.g., 10 ppm) on the books. Thus, workers were already afforded some degree of protection from benzene's chronic exposure effects. The Supreme Court required OSHA to demonstrate a *need* for the *new* 1 ppm standard based on an explicit finding that a significant risk exists at the current 10 ppm standard. This is an important problem because OSHA currently has on the books exposure standards for approximately 400 toxic chemicals that it automatically adopted in 1971 subsequent to the enactment of the OSH Act. These standards were the voluntary "consensus" and federal standards in effect in 1970. It may be particularly difficult for OSHA to demonstrate a significant risk with respect to many of these toxic chemical standards because of long latency periods associated with many significant health effects such as cancer.

Burden of Proof[15] Stevens, Burger, Stewart, and Powell put the burden on OSHA to demonstrate the "need" for a proposed standard. The plurality holds that OSHA is not authorized by Congress to prevent exposures to agents which may (or may not) present significant risks. Rather, they argue that OSHA's authority is to set standards for *toxic* chemicals and *harmful* physical agents. Thus, *OSHA* must find, as a threshold matter, that low level exposures to benzene are toxic before a new standard may be considered to be "reasonably necessary." The Court asked for "demonstrable health effects" or "evidence of an increased risk" due to benzene exposures at or below 10 ppm. The Court criticized the agency because OSHA made no finding that exposure to benzene at 10 ppm had ever *in fact* caused leukemia. But the Justices explicitly did *not* express an opinion on "the more difficult question of what factual determinations would warrant a conclusion that significant risks are present."

The plurality opinion, however, did not seem to take into account or understand the scientific-medical aspects of the case when it demanded OSHA to show some empirical evidence documenting a leukemia risk at 10 ppm. That 10 ppm exposure level had been established by OSHA only in 1971. This would be an insufficient time period to evaluate the effectiveness of the standard. Leukemia can appear nine to 20 years after exposure to benzene has ceased.

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[15] "Burden of proof" is a legal concept with important ramifications. The party with the burden is generally at a disadvantage. The courts have sometimes placed the burden on the agency issuing the standard and other times have placed the burden on challengers. There is no settled rule of law.

Many of benzene's health effects are irreversible and often fatal (e.g., aplastic anemia). It is far too soon to know exactly how safe the existing 10 ppm standard will prove to be, particularly since OSHA is directed by Section 6(b)(5) to set standards which assure no material health impairments will result even from regulated exposure throughout working life.

SECTION 6(b)(5) AND FEASIBILITY IN GENERAL

The Court in Industrial Union summarized Congressional thinking about the feasibility requirements included in the OSH Act: "Congress does not appear to have intended to protect employees by putting their employers out of business--either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible."[16]

The following review of feasibility is divided into two sections--one discussing technological feasibility and one discussing economic feasibility. This coincides with the treatment given feasibility by the courts in their discussions of the issue. However, no court has indicated that an OSHA standard would be invalidated solely because it was deemed economically infeasible. Furthermore, the OSH Act treats "feasibility" as a single concept. Therefore, "economic feasibility" and "technological feasibility" should be viewed as two separate considerations which OSHA addresses under the general feasibility requirement.

Technological Feasibility. Technological feasibility is a crucial consideration in setting an occupational safety and health standard. Since the OSH Act does not set guidelines for determining what is feasible, the concept has not been completely fleshed-out, but the broad outlines are established. In The Society of the Plastics Industry, Inc. v OSHA,[17] the Second Circuit Court of Appeals seemed to interpret technological feasibility as a broad concept which entailed at least three components:

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[16] Industrial Union, op. cit. at p. 1639. It is interesting to note some dicta in AFL-CIO v. Brennan, 3 OSHC 1820, 1828 (3d Cir. 1975) which tempers this statement: "We do not question that there are industrial activities involving hazards so great and of such little social utility that the Secretary would be justified in concluding that their total prohibition is proper if there is no technologically feasible method of eliminating the operational hazard." While the OSH Act places some limits on what standards can require from a technological and economic standpoint, not all acts dealing with human health are so temperate. Regarding the Clean Air Act Amendments of 1970, one court has noted that "Congress made it clear that consideration of economic cost or technical feasibility were always to be subordinate to consideration of public health." NRDC v. EPA, 489 F.2d 390, 411-412 (1974). See also, Regulatory Analysis Methods: A Review of Past Health-Related Efforts, "Appendix B: Legal Issues For Regulatory Analysis" (Draft) (ICF Inc., 1979), for a discussion of the feasibility and standard of review issues.

[17] 509 F.2d 1301, 2 OSHC 1496 (2d Cir.) (vinyl chloride) cert. denied, 421 U.S. 992, 3 OSHC 1195 (1975).

- engineering technology;
- work practices; and
- personal protective gear.

The court rejected claims that a 1 ppm permissible exposure level (PEL) for vinyl chloride was infeasible because engineering controls could never achieve the 1 ppm level. The Court reasoned that:

- the industry underestimated its technological potential;[18] and
- there were work practice controls and personal protective gear which supplement the engineering controls, and which could be combined to "definitely" attain the goal of the lowest detectable level.[19]

The court stated: "In the area of safety the Secretary is not restricted by the status quo. He may raise standards which require improvements in existing technologies or which require the development of new technology, and he is not limited to issuing standards based solely on devices already fully developed."[20]

The Third Circuit, in AFL-CIO v Brennan,[21] asserted that OSHA could consider technological feasibility with regard to non-toxic hazards: "If the Secretary may consider technological feasibility with respect to the elimination of hazards from toxic materials, then a fortiori he must be permitted to do so with respect to other hazards under the more general language of Sec. 6(a)."[22] This court also interpreted technological feasibility to include any appropriate technology which "looms on today's horizon."[23] Technological feasibility, therefore, "implies consideration both of existing technological capabilities and imminent advances in the art."[24]

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[18] The court used the industry's past experience with decreasing exposure levels to support its (the court's) faith in the industry's technological capability.

[19] Society of Plastics, op. cit., at p. 1502.

[20] Id. This same technology-forcing is found, in varying degrees, elsewhere. For example, the Clean Air Act has been interpreted to require technological innovation. International Harvester Co. v. Ruckleshaus, 478 F.2d 615, 628-629 (D.C. Cir. 1973).

[21] 530 F.2d 109, 3 OSHC 1820 (3d Cir. 1975).

[22] Id., at p. 1828.

In American Iron and Steel Institute, et al. v OSHA,[25] technological feasibility was further explained. The Court again relied on the industry's experience in decreasing exposure levels and indicated that this trend pointed to the industry's potential technological capabilities. The Court was convinced by evidence accumulated by the Secretary that the new PEL could be achieved if the industry would apply itself to the task.[26] In any event, the Court made it clear that the certainty of technological feasibility need not be absolute:

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[23] Id., at p. 1829. Note, however, that the Fifth Circuit has used its benzene decision (American Petroleum Institute, et al. v. OSHA, 581 F.2d 493 (1978)) as authority to limit what may be required of employers in this respect: "The Secretary may promulgate a standard requiring employers to implement technological methods not yet developed but looming on the horizon only if the Secretary can show by substantial evidence that the employment conditions imposed by the proposed standard are reasonably necessary to provide safe or healthful places of employment," Marshall v. West Point Pepperell, Inc. 588 F.2d 979 (5th Cir. 1979). This reasoning was upheld on other terms by the Supreme Court, ___ U.S. ___ (1980).

[24] Id. The concept of "imminent advances" indicates that time is an important factor--affecting both technological and economic feasibility. A standard with a five-year lead-in period might be considered technologically feasible, whereas the same substantive standard requiring immediate compliance might not be feasible. Similarly, a lead-in time might bring within the realm of economic feasibility a standard otherwise infeasible.

[25] 577 F.2d 825, 6 OSHC 1451 (3d Cir. 1978) (coke oven emissions).

[26] The PEL was based on results from tests at one of the industry's best facilities for limiting exposure levels. There also was much testimony highlighting "innovative technology currently in the experimental stage readily adaptable to old(er) facilities." Id., p. 1458. While this might be considered support for the general conclusion that technological feasibility encompasses PELs based on industry-leader experience, the coke oven case involved a unique situation:

> (T)he coke oven industry is unusually homogeneous; nearly all facilities conform to the same basic design. Therefore, the control capabilities of the industry leader fairly approximated what other facilities could accomplish. There are few instances in which the homogeneity of the regulated industry is so pronounced.

Berger and Riskin, "Economic and Technological Feasibility..." 7 Ecology Law Quarterly, op. cit.

- Quoting from its decision in Atlantic and Gulf Stevedores v. OSHA, the Court stated that "it may become evident that a particular safety and health standard is ... technologically infeasible, or otherwise unreasonable, only after employers have made a good faith effort to comply."[27]

- The Court noted that under appropriate conditions, variances were available when engineering controls and work practices do not bring about the required PEL.

A recent decision by the D.C. Circuit adds weight to the principle that OSHA need not show with absolute certainty that every firm in the industry can meet the standard. In order to demonstrate feasibility, however, OSHA must show that current technology has "conceived" of strategies or devices that are "likely" to be capable of meeting the PEL and that the industry will generally be capable of adapting those strategies or devices.[28]

Although the courts have given OSHA considerable latitude in requiring technological improvement, limits do exist. In American Iron and Steel Institute, the Court invalidated a provision of the coke oven emission standard which required employers to "research, develop and implement any other engineering and work practice controls necessary to reduce exposure to or below the permissible exposure limit." In effect, employers had to engage in research and development if the controls required by OSHA did not achieve the PEL. The court invalidated this requirement on two grounds:

- the OSH Act did not permit OSHA "to place an affirmative duty on each employer to research and develop new technology"; and

- the requirement was not specific enough for a determination to be made whether or not it was feasible. (p. 1461)

This decision does not restrain the latitude in this area previously given by the courts to OSHA.

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[27] 534 F.2d 541, OSHC 1061 (1976).

[28] United Steel Workers of America v. Marshall, 8 OSHC 1810, 1864, 1868 (D.C. Cir. 1980) (The Court was reviewing OSHA's lead standard and upheld it.). Note, however that the Court implicitly limited its leniency regarding the uncertainty of feasibility to the pre-enforcement stage (p.1868). In an earlier case (AFL-CIO v. Marshall, 617 F.2d 636, 7 OSHC 1775 (1979) (upholding most of the cotton dust standard)), the D.C. Circuit indicated that one situation in which technological feasibility requirements (and presumably its certainty) were satisfied was where much of the affected industry had demonstrated its ability to meet the PEL (1788).

Economic Feasibility. It appears that no court has required in explicit terms that OSHA must consider economic factors in determining feasibility. It is clear, however, that OSHA considers economic factors to be crucial in the promulgation of standards, and that the courts expect the subject to be treated by OSHA. In all practicality, then, the issue of the economic effect of a standard must be treated by OSHA.

Perhaps the simplest explanation of feasibility was given by the Court in Industrial Union: "(I)t would comport with common usage to say that a standard that is prohibitively expensive is not 'feasible'."[29] This is in keeping with the Court's interpretation of the OSH Act's legislative history that "practical considerations can temper requirements."[30] Industrial Union established the tone of subsequent judicial discussions of economic feasibility. The salient principles espoused by the court are:

- A standard can substantially increase production costs without rendering the standard infeasible.
- A standard can be economically feasible even if it adversely affects profit margins.
- A standard can result in the "economic demise of an employer who has lagged behind the rest of the industry in protecting the health and safety of employees and is consequently financially unable to comply with new standards as quickly as other employers."
- If economic demise assumes industry-wide proportions, economic feasibility is called into question.

The Court in AFL-CIO v Brennan endorsed as "a proper construction" of the OSH Act, the Industrial Union court's practical constraints on feasibility.[31] The Court in AFL-CIO intimated that the economically infeasible standard is characterized by "massive economic dislocation." The court suggested that economic infeasibility would result in widespread evasion of a standard, and that enforcement difficulties would be insurmountable. Thus, an economically infeasible standard would not be effective because compliance could not be enforced.

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[29] 499 F.2d 467, 1 OSHC 1631, 1639 (emphasis added).

[30] Id. One commentator suggests that "the concept of economic feasibility as a qualification to the mandate for absolute safety would appear to encompass only the most extreme kind of costs--those so large as to put significant portions of entire industries out of business." R.S. Smith, The Occupational Safety and Health Act (AEI: Washington, D.C. 1976).

[31] 530 F.2d 109, 3 OSHC 1820, 1830.

In American Iron and Steel Institute, et al. v OSHA, the court refers to "a very practical necessity to weigh economic costs."[32] The record in this case had abundant information regarding economic feasibility. Both the Secretary and industry groups produced studies of the coke oven emission standard's financial impact. Some representative findings were:[33]

- There would be an estimated 13 percent decline in industry earnings per share.
- Cost to consumers would rise.
- Imported steel would capture a greater share of the U.S. market.

The Court indicated, however, that its own careful weighing of the financial impact on the industry did not show that the industry's financial burden would even approach the "massive dislocation" which had been set as the benchmark for the "economically infeasible standard." The Court further found that "the Secretary had sufficient data from which he could properly balance the cost to industry against the health needs of its employees."[34] The Court discusses the balancing of costs and needs without specifically separating it from "massive economic dislocation" as an element of economic feasibility. The Court upheld the Secretary's reasoning and practice as described in the following excerpt from the Secretary's statement of reason:

> Moreover, although we cannot rationally quantify in dollars the benefit of the standard, careful consideration has been given to the question of whether these substantial costs are justified in the light of the hazards. OSHA concludes that these costs are necessary in order

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[32] 577 F.2d 825, 6 OSHC 1451, 1458.

[33] Id. p. 1459.

[34] Id. (emphasis supplied). It is not clear whether the court interpreted this balancing as support for the standards' feasibility or whether it cites OSHA's balancing as evidence that OSHA did in fact "inquire into the economic feasibility of the standard".

> to adequately protect employees from the hazards associated with coke oven emissions.[15]

It is fair to suggest that balancing came within the rule that "practical considerations can temper protective requirements" laid down by the Industrial Union Department court. If so, it would be one of the factors OSHA could, but was not required to, consider in deciding whether a standard is economically feasible. The court concluded that it had no basis to find that OSHA had not inquired into the economic feasibility of the standard, or that the standard was infeasible. The Court also gave extra credence to the United Steelworkers' support of the standard, reasoning that the workers had as much to lose as anyone if the standard was economically infeasible.

Summary of Feasibility: Technological and Economic

The concept of technological feasibility, as developed by the courts, allows OSHA considerable latitude:

- An occupational safety and health standard can be technology-forcing. The standard can go beyond the technological status quo and require current technology to be improved and new technology to be developed.
- Technological feasibility is not achieved strictly through engineering controls, but encompasses work practices and personal protective gear.
- The courts will not require that a standard's technological feasibility be absolutely certain before it is promulgated.

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[15] Id., pp. 1459-1460. Although the Supreme Court has not directly addressed the economic feasibility issue, it has granted review and heard oral argument in the cotton dust litigation. The Court has focused its review on the economic issues. No court, to date, has held that OSHA must conduct a formal cost-benefit analysis before it promulgates a standard. In the cotton dust litigation, the D.C. Circuit stated that "Congress concluded that the benefits of health protection warranted the expense of an effective standard.... Further, cost-benefit analysis would not necessarily improve agency health and safety determinations. These techniques require the expression of costs, benefits and performance in often arbitrary, measureable terms. They may hide assumptions and qualifications in the seeming objectivity of numerical estimates. Especially where a policy aims to protect the health and lives of thousands of people, the difficulties in comparing widely dispersed benefits with more concentrated and calculable costs may overwhelm the advantages of such analysis." (Footnotes omitted) AFL-CIO v. Marshall, op. cit., pp. 1792-1794.

There are limits, however, on OSHA's technology-forcing authority. It seems clear that the required technology cannot be too speculative or remote, and that affirmative research and development burdens cannot be placed on individual employers.

Economic feasibility includes a number of components. The courts have indicated that economic feasibility is not destroyed by:

- an increase in production costs;
- a decrease in profit margins;
- the demise of an individual employer;
- a decrease in earnings per share; and
- a rise in consumer cost (inflation).

What does seem to be the benchmark of economic infeasibility is a "massive economic dislocation" of the industry affected by the standard. There are no outer bounds set by the courts, but factors which can be considered in addition to those listed above are:

- Effect on competition--foreign, inter-industry, and intra-industry; and

- Enforcement difficulties.

OSHA is apparently not limited by these factors, and may consider other factors in addition to or in lieu of these factors. Economic feasibility, therefore, does not require the financial burden to be minimal or even reasonable, but it does require the burden to stop short of causing a massive disruption of the target industry.

THE STANDARD OF REVIEW: SECTION 6(f)

The standard of review is a legal term which refers to the test which courts apply to agency actions such as regulating toxic substance exposures. Courts use different tests for different situations. In general, a "factual" determination is reviewed under a different test than is a "policy" determination:

- The substantial evidence test is usually applied to adjudicatory proceedings or formal rulemaking.[14]

  The questions arising in these situations are usually factual in nature. A definition of "substantial evidence" was given recently by the Fifth Circuit--substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion."[17] Thus, when an administrative action (such as a regulation) is based on a factual record, some facts contained in the record must support the action taken even though other facts in the record would support a totally opposite conclusion.

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[14] Industrial Union Department, AFL-CIO v. Hodgson. 499 F.2d 467, 1 OSHC 1631, 1635 (D.C. Cir. 1974).

- The arbitrary or irrationality test is usually applied to "essentially legislative tasks,"--i.e., policy determinations. That is, a workplace standard cannot be arbitrary or irrational.[18]

Another way of looking at these two "yardsticks" was articulated by the D.C. Circuit Court:

- A choice based on determinable facts must be supported by evidence in the record.
- A choice based on policy judgments must be explicitly based on considerations which the administrator found persuasive.

Which standard of review is chosen is theoretically important, because each demands that different requirements be met by the record on which an OSHA standard is based. In the final analysis it is not the title applied to the review used by the Court, but the substance of the review that is important.[39] The courts have given some guidance as to the characteristics of a legislative-policy determination and a factual determination. These characteristics are discussed below.

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[17] Marshall v. West Point Pepperell, Inc., 588 F.2d 979, 985 (1979). Another articulation is that evidence is "substantial" when "'from it (the evidence) an inference of the fact may be drawn reasonably.'" American Iron and Steel Institute, et al v. OSHA, 477 F.2d 825, 6 OSHC 1451, 1455 (3rd Cir. 1978). The Court was quoting Schwarz, Administrative Law 595 (1977). One commentator has suggested a practical view of when to apply substantial evidence review: "The ability to apply the substantial evidence rule obviously depends upon the degree to which a particular decision is susceptible to evidentiary development." Taylor, Donald, "Reasonable Rulemaking Under OSHA: Is It Feasible?" 9 St. Mary's Law Journal 215, 228 (1977).

[18] Industrial Union Department, AFL-CIO v. Hodgson, 1 OSHC 1631, 1637. The agency is to make its policy determinations in such "'a manner calculated to negate the dangers of arbitrariness and irrationality in the formulation of rules for general application in the future'," Industrial Union Department, op. cit., p. 1637; and Society of the Plastics Industry, Inc. v. OSHA, 2 OSHC 1496, 1498, (2d Cir. 1975) (vinyl chloride); and a legislative task must be carried out "in a manner reasonable under the state of the record..." American Petroleum Institute, et al. v. OSHA, 6 OSHC 1959, 1961 (5th Cir. 1978) (benzene). Note that the 5th Circuit recently interpreted Section 6(f) of the OSH Act to require application of the "substantial evidence" standard to OSHA's policy (or legislative) determinations as well as to its factual determinations. Texas Independent Ginners Assoc. v. Marshall, 8 OSHC 2205, 2209-2210 (5th Cir. 1980).

The Difference Between "Policy" and "Factual" Determinations

Policy Determinations. OSHA policy determinations were deemed to exist in the following kinds of situations:

- When a particular question is on the "frontiers of scientific knowledge" and the data relevant to such a question is insufficient "to make a fully informed factual determination" a policy situation exists;[40] and

- When a standard is set and "reliable data is not currently available with respect to the precisely predictable health effects of various levels of exposure" to some hazardous substance, the final setting of a permissible exposure level is a policy choice to be made by the Secretary.[41] The Secretary may rely on "respectable opinion" that such levels do exist.[42]

This recognition that policy decisions confound the application of tests traditionally applied to factual determinations has been recognized in regulatory arenas other than occupational safety and health:

> Looking to the future, and commanded by Congress to make policy, a rulemaking agency necessarily deals less with "evidentiary" disputes than with normative conflicts, projections from imperfect data, experiments and simulations, educated predictions, differing assessments of possible risks, and the like. The process is *quasi*-legislative in

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[39] 1 OSHC at p. 1637.

[40] *Id*. (The Court also quoted the Supreme Court's language in the *Permian Basis Area Rate Case*, 390 U.S. 747, 811 (1968): "Where existing methodology or research in a new area of regulation is deficient, the agency necessarily enjoys broad discretion to attempt to formulate a solution to the best of its ability on the basis of available information.")

[41] *Id*.; *Society of the Plastics Industry*, *op*. *cit*., p. 1502.

[42] *Synthetic Organic Chemical Manufacturers Association v. Brennan*, 506 F.2d 385, *cert*. *denied*, 423 U.S. 886 (1975); 2 OSHC 1402, 1406 (3rd Cir. 1974).

character, and one will search it in vain for those intermediate "findings" of fact which mark the midway point in an adjudicator's linear march from raw evidence to single, ultimate conclusion."[43]

Factual Determinations. If the Secretary's "task consisted primarily of evaluating data and drawing conclusions" from that data, the court will apply the substantial evidence test.[44] OSHA's determinations were characterized as factual, subject to the substantial evidence review test, in the following situations:

- where the hearings regarding revocation of a standard had been rich in statistical evidence submitted by parties on both sides of the controversy;[45] and
- where the Secretary's determination had been based upon "'overwhelming scientific evidence'" including "chemical analysis and various epidemiological studies;" testimony by the Assistant Director of NIOSH; a 1970 report to the Surgeon General entitled "Evaluation of Environmental Carcinogens" by the ad hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens (summarizing the opinions of numerous experts), and the majority report of the Secretary's Advisory Committee.[46]

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[43] Amoco Oil Co. v. EPA, 501 F.2d 722, 735 (D.C. Cir. 1974) (lead-free gasoline). Cases involving other regulatory agencies confirm this viewpoint (see, for example, The Superior Oil Co. v. FERC, 563 F.2d 191, 201 (5th Cir. 1977)).

[44] Industrial Union, op. cit., at p. 1637 (asbestos).

[45] AFL-CIO v. Brennan, 530 F.23 109, 3 OSH 1820 (3d Cir. 1975). This case involved revocation of the "no hands in die" requirement of the mechanical power press standard.

[46] American Iron and Steel Institute, et al. v. OSHA, 577 F.2d 825, 6 OSHC 1451, 1455-1456 (3d Cir. 1978) (coke ovens). This standard, however, appears to be an exception in regard to the detail contained in the record: "OSHA took a long time to prepare this standard, held unusually extensive promulgation hearings, and compiled an extraordinarily detailed record on these issues. If OSHA begins to set more standards, it will not have as much time and resources to devote to any one hazard." Berger, Jeffrey, and Riskin, Steven, "Economic and Technological Feasibility in Regulating Toxic Substances Under the Occupational Safety and Health Act," 7 Ecology Law Quarterly, 285, 351 (1978).

It should be noted, however, that while the record may contain great detail about a decision, it still may involve policy judgments and extrapolations, and thus be subject to the arbitrary and capricious standard of review.[47]

In summary, in Industrial Union, the Court made an interesting observation which almost had the appearance of an institutional quid pro quo. OSHA had expanded its informal hearings to include elements which provided a more detailed record (i.e., easier for a court to apply the substantial evidence test) than strictly required by the OSH Act. The court thought "it equally the part of wisdom and restraint on our part to show a comparable flexibility, and to be always mindful that at least some legislative judgments cannot be anchored securely and solely in demonstrable fact."[48] What seems to be acknowledged, therefore, is that OSHA will try to assemble as complete a record as possible so a reviewing court's task will be facilitated, and that the court will give due regard to the Secretary's policy determinations without requiring too much from the record or according false precision to the facts provided. "What we are entitled to at all events is a careful identification by the Secretary ... of the reasons why he chooses to follow one course rather than another."[49]

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[47] As the Supreme Court has indicated in another regulatory area, what is important is the nature of the decision:

> To the extent that factual determinations were involved in the Commission's decision to grandfather most existing combinations, they were primarily of a judgmental or predictive nature . . . In such circumstances, complete factual support in the record for the Commission's judgment or prediction is not possible or required; "a forecast of the direction in which future public interest lies necessarily involves deductions based on the expert knowledge of the agency." FCC v. National Citizens Comm. for Broadcasting, 436 U.S. 775, 813-14 (1978).

Some of the factual determinations to which the court referred were "whether a divestiture requirement would result in trading of stations with out-of-town owners; whether new owners would perform as well as existing cross owners, either in the short run or in the long run; whether losses to existing owners would result from forced sales; whether such losses would discourage future investment in quality programming; and whether new owners would have sufficient working capital to finance local programming."

[48] Id., at p. 1638.

[49] Id., at p. 1637.

OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR TOXIC AND HAZARDOUS SUBSTANCES -- REGULATORY REVIEW

This paper reviews the Occupational Safety and Health Standards for Toxic and Hazardous Substances promulgated or proposed under the authority of Section 6 of the Occupational Safety and Health Act (OSH Act). The paper will:

- discuss OSHA's approach to designating chemicals as toxic and hazardous substances;
- identify the chemical substances which have been designated for regulation as toxic and hazardous substances;
- review the health standards established by OSHA; and
- specify the basis for the standards.

OVERVIEW

In accordance with Section 6(a) of the OSH Act, OSHA initially designated 400 chemical substances as air contaminants and promulgated exposure standards for them (29 CFR 1910.1000). Appendix A lists the 400 chemicals and their threshold limit values in units of milligrams per cubic meter of air (mg/m^3) and parts per million (ppm). Exposures to substances are limited to acceptable ceiling concentrations and/or 8-hour time weighted average concentrations. See the OSHA Statutory Review for a discussion of the authority for this action.

Through Section 6(b) proceedings, OSHA designated and promulgated health standards for these twenty-three substances:

(1) Asbestos
(2) 4-Aminodiphenyl
(3) 4-Nitrobiphenyl
(4) Alpha-Napthylamine
(5) Beta-Napthylamine
(6) 4-4'- Methylene bis (2-chloro-aniline)[1]

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[1] 4-4'- Methylene bis (2-chloro-aniline), was deleted from the regulations on August 20, 1976 (41 FR 35184) following the U.S. Court of Appeals (Third Circuit) remand of the standard to OSHA. The Court held in Synthetic Organic Chemical Manufacturers Association, et. al., v. Brennan (2 OSHC 1402) that procedural requirements of the OSH Act were not met by the 4-4 Methylene bis (2-chloro-aniline) standard. The Court found that OSHA violated the time-schedule procedures outlined in Section 6(b) of the OSH Act because the 4-4 Methylene bis (2-chloro-aniline) proposed rule was published before the advisory committee had submitted its report.

(7) Methyl Chloromethyl Ether
(8) 3,3;-Dichlorobenzidine (and its salts)
(9) bis-Chloromethyl Ether
(10) Benzidine
(11) Ethyleneimine
(12) Beta-Propiolactone
(13) 2-Acetylaminofluorene
(14) 4-Dimethylaminoazobenzene
(15) N-Nitrosodimethylamine
(16) Vinyl Chloride
(17) Inorganic Arsenic
(18) Lead
(19) Benzene (vacated by the Supreme Court, 7/2/80)
(20) Coke oven emissions
(21) Cotton dust
(21a) Cotton dust in cotton gins (vacated)
(22) 1,2-dibromo-3-chloropropane (DBCP)
(23) Acrylonitrile

The standards were promulgated as Subpart Z -- Toxic and Hazardous Substances of Title 29 Code of Federal Regulations. OSHA also has proposed health standards for beryllium, sulfur dioxide, trichloroethylene, toluene, ammonia, and a revised asbestos standard.

Exhibit 1-3 presents a chronological review of the regulatory actions involved with OSHA's health standards. The date and *Federal Register* citation are included for each emergency temporary and permanent standard promulgated. In addition, the date and citation for the proposed beryllium and asbestos standards are listed.

Exhibit 1-4 summarizes the various criteria used by OSHA to designate chemical substances for regulation. OSHA relied on two primary criteria:

(1) Health Effects
(2) Feasibility

The three types of health effects considered were acute health effects, chronic health effects (non-carcinogenic), and carcinogenicity. In some cases, OSHA relied only on acute health effects to designate a chemical substance for regulation (e.g., cotton dust in cotton gins) whereas in other cases, OSHA relied solely on evidence of carcinogenicity of a chemical (e.g., inorganic arsenic).

Exhibit 1-4 also lists the types of data, i.e., epidemiological, animal bioassay, short-term assay, or chemical analysis, on which OSHA based determinations that a chemical substance was a human carcinogen.

When carcinogenicity of a chemical served as a criterion for standard setting, OSHA followed a general policy that if safe exposure levels for carcinogenic substances could not be scientifically determined, standards were established at the *lowest feasible level*. In determining the lowest feasible level, OSHA considered *economic* and *technological feasibility* for each chemical substance regulated.

EXHIBIT 1-3

REGULATORY CHRONOLOGY: OCCUPATIONAL SAFETY AND HEALTH STANDARDS FOR TOXIC AND HAZARDOUS SUBSTANCES

Date	Regulatory Action	Federal Register Citation
May 29, 1971	400 Air Contaminant Standards promulgated	36 FR 10466
December 7, 1971	Asbestos Emergency Temporary Standard issued	36 FR 23207
June 7, 1972	Asbestos Permanent Standard promulgated	37 FR 11318
May 3, 1973	Emergency Temporary Standards issued for 14 Carcinogens [including 4,4'Methylene-bis(2-chloroaniline) (MBOCA)]	38 FR 10929
January 29, 1974	Standards promulgated for 14 Carcinogens (including MBOCA)	39 FR 3756
April 5, 1974	Vinyl Chloride Emergency Temporary Standard issued	39 FR 12342
October 4, 1974	Vinyl Chloride Permanent Standard promulgated	39 FR 35890
December 1974	MBOCA Standard vacated by Fifth Circuit Court of Appeals	
February 5, 1975	Standard reproposed for MBOCA	40 FR 4932
October 1, 1975	Proposed Revisions to Asbestos Standard	40 FR 47652
October 6, 1975	Toluene Standard proposed	40 FR 46206
October 17, 1975	Beryllium Standard proposed	40 FR 48814
October 29, 1975	Trichloroethylene Standard proposed	40 FR 49032
November 24, 1975	Sulfur Dioxide Standard proposed	40 FR 54520
August 20, 1976	MBOCA deleted from Carcinogen Standards	41 FR 35184
October 22, 1976	Coke Oven Emissions Permanent Standard promulgated	41 FR 46742
May 12, 1977	Benzene Emergency Temporary Standard issued	42 FR 22516
September 9, 1977	DBCP Emergency Temporary Standard issued	42 FR 45536
January 17, 1978	Acrylonitrile Emergency Temporary Standard issued	43 FR 2586
February 10, 1978	Benzene Permanent Standard promulgated	43 FR 5918
March 17, 1978	DBCP Permanent Standard promulgated	43 FR 11514
May 5, 1978	Inorganic Arsenic Permanent Standard promulgated	43 FR 19624
June 23, 1978	Cotton Dust Permanent Standard promulgated	43 FR 27350
June 23, 1978	Cotton Dust In Cotton Gins Standard promulgated	43 FR 27418
October 3, 1978	Acrylonitrile Permanent Standard promulgated	43 FR 45672
November 14, 1978	Lead Permanent Standard promulgated	43 FR 52952
January 22, 1980	OSHA Cancer Policy promulgated	43 FR 5002
July 2, 1980	Benzene Standard invalidated by Supreme Court	
August 12, 1980	"Candidate" Carcinogens List published under 1/22/80 Generic Carcinogens Policy	45 FR 53672
November 17, 1980	Cotton Ginning Standard invalidated by Fifth Circuit Court of Appeals	
January 16, 1981	Hazard Identification (labeling) Standards proposed	46 FR 4412
January 29, 1981	Proposed Labeling Standard withdrawn	46 FR 12020

EXHIBIT 1-4

OSHA'S DESIGNATION CRITERIA FOR TOXIC AND HAZARDOUS SUBSTANCES

Criteria	Asbestos	14 Carcinogens	Vinyl Chloride	Inorganic Arsenic	Lead	Benzene	Coke Oven Emissions	Cotton Dust	DBCP	Cotton Dust in Gins	Acrylonitrile	Beryllium
(1) HEALTH EFFECTS	x	x	x	x	x	x	x	x	x	x	x	x
Acute	x				x			x		x		x
Chronic (non-carcinogenic)			x		x	x	x	x	x			x
Carcinogenicity	x[a]	x	x	x		x	x		x		x	x
- epidemiological data	x	x	x	x		x	x			x		
- animal experimental data		x	x			x	x		x		x	x
- short-term assays									x			
- chemical analyses							x					
(2) FEASIBILITY	x	x	x	x	x	x	x	x	x	x	x	x

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[a] Considered in proposed revised standard only.

CHEMICAL-BY-CHEMICAL ANALYSIS

This section reviews each chemical substance designated by OSHA for regulation as a toxic or hazardous substance under Section 6(b) of the OSH Act. The criteria used by OSHA to designate the substance for regulation and the rationale behind each standard is discussed.

Asbestos

Basis for Designation

Asbestos[2] was designated for regulation under Section 6(b) because this substance at high concentrations is causally related to asbestosis (lung-scarring). At the time of designation, it had been well established that asbestosis was a major cause of disability and death among workers regularly exposed to asbestos dust. A British Occupational Hygiene Society Study[3] suggested that the incidence of asbestosis would be markedly diminished by the reduction of occupational exposure in factories and during end product use.

Reports also indicated that workers exposed to asbestos during factory production of asbestos products and in their subsequent use were at increased risk of developing several types of cancer, including lung cancer and mesothelioma. The specific concentration level below which exposure to asbestos was safe was disputed. Because of the long lapse of time between onset of exposure and biological manifestations, OSHA did not have accurate measures of the levels of exposure which occurred 20 or 30 years ago and subsequently gave rise to cancer. The relationship between extent of asbestos exposure and risk of asbestos-associated cancer had not been defined. As a result, OSHA proposed asbestos exposure levels to prevent asbestosis and "hoped" the permissible exposure levels would be restrictive enough to also minimize asbestos-associated cancer.[4]

Standards

A standard for occupational exposure to asbestos was included in the initial promulgation of OSHA air contaminant standards (36 FR 10506, May 29, 1971). This standard was derived from a 1969 federal standard issued under the Walsh-Healy Public Contracts Act. The standard established an exposure limit of 12 asbestos fibers (greater than 5 microns in length) per milliliter or 2 million particles per cubic foot of air.

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[2] "'Asbestos' includes chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite." (29 CFR 1910.1001(a)(1)).

[3] "Hygiene Standards for Chrysotile Asbestos for the Prevention of Asbestosis", British Occupational Hygiene Society, 1968.

[4] Proposed Standard for Occupational Exposure to Asbestos, October 16, 1975, (40 FR 47652).

In accordance with Section 6(c) of the OSH Act, an emergency temporary standard was first issued for asbestos (36 FR 23207, December 7, 1971). This standard was based on OSHA's determination that employees were exposed to "grave danger" from exposure to asbestos. A permanent standard was promulgated on June 7, 1972 (37 FR 11318) which established an 8-hour time-weighted average (TWA) concentration exposure limit of five fibers (longer than 5 micrometers) per cubic centimeter of air, and a ceiling limitation against any exposure in excess of ten such fibers per cubic centimeter. Furthermore, the standard provided that the 8-hour TWA be reduced to two fibers, effective July 1, 1976. The regulation specified engineering methods and work practices for compliance with the standards. In addition, cautionary sign specifications and labeling requirements were included in the regulations.

The NIOSH Criteria Document for asbestos had pointed out that most medical opinion was divided between advocating a two-fiber standard or a five-fiber standard.[5] OSHA decided to promulgate the more restrictive two-fiber standard, with a ceiling value of 10 fibers/cc as the permanent standard after July 1, 1976 because:[6]

- there must be one standard governing exposure to all varieties of asbestos and all workplace exposures;
- some employees with regular exposure to asbestos had already accumulated great doses of asbestos fibers, due to higher levels of exposure in the past;
- it appeared that levels of exposure which might be safe with regard to asbestosis might not be safe with regard to mesothelioma;
- the statute required the protection of every employee, even one who might have regular exposure to asbestos during a working life which might reach or even exceed 40 years;
- the conflict in the medical evidence should be resolved in favor of the health of employees.

An interim standard (permitted until July 1, 1976) of five fibers was instituted to give employers a transitional period in which to make the necessary arrangements for complying with the more stringent two-fiber standard.

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[5] "Recommendations for An Occupational Exposure Standard for Asbestos by the National Institute for Occupational Safety and Health", 1971.

[6] Preamble to the Standard for Exposure to Asbestos Dust, 37 FR 11318, June 7, 1972.

Prior to its adoption, OSHA considered the feasibility of the standard by identifying those industries which would meet compliance difficulties (e.g., textile, manufacturing, and marine installation). After evaluating the extent of redesign and relocation of equipment necessary for these industries to comply, OSHA determined that the transitional five-fiber standard would "provide all employers a reasonable time to comply" (37 FR 11319, June 7, 1972) with the two-fiber standard. Furthermore, OSHA determined that technological controls and appropriate work practices would provide the "best protection against asbestos fibers feasible" (37 FR 11319).

OSHA proposed revisions to the asbestos standard in October 1975 (40 FR 47652). To date, no final revisions have been promulgated.[7]

The proposed revisions were based on new information concerning the toxic effects of asbestos and on the experience gained by OSHA through three years of enforcement and administration of the current asbestos standard. Specifically, OSHA identified the widening spectrum of cancers associated with asbestos exposure and the various manifestations of asbestos disease in individuals exposed to relatively low concentrations of dust as the primary factors necessitating a revised asbestos standard. The proposal intended to refocus the primary function of the standard from preventing asbestosis to reducing the incidence of asbestos-associated cancer, particularly mesothelioma.

The proposal, if promulgated, would revise the definition of "asbestos" in the present standard. It would add to the existing definition of "asbestos" the phrase "and every product containing any of these minerals". This proposed change reflected OSHA's "concern for the morphology and toxicity of the regulated substance rather than its geologic or mineralogic origin" (40 FR 47652).

OSHA also proposed to lower the 8-hour exposure limit (TWA) to 0.5 asbestos fibers per cubic centimeter and to lower the ceiling exposure to 5 asbestos fibers per cubic centimeter. The proposed change was based on OSHA's determination from new medical and scientific evidence that asbestos was a human carcinogen. As a human carcinogen, there is no known safe exposure level for asbestos. Consequently, "there should be no detectable concentrations" in the workplace (40 FR 47652). However, OSHA is required to consider technological and economic factors when setting permissible exposure levels so the proposed standards were established at the lowest feasible level.

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[7] NIOSH recently recommended a 0.1 asbestos fibers per cubic centimeter 8-hour exposure limit. OSHA is examining this recommendation to see if it is technologically and economically feasible. This information is from discussions with OSHA's Health Standards Staff.

Fourteen Carcinogens

Overview

The chemicals listed in Exhibit 1-5 were designated for regulation under Section 6(b) of the OSH Act because OSHA considered them to be carcinogens. Another chemical, 4-4'- Methylene bis (2-chloro-aniline), was designated for regulation because of its carcinogenic potential, but was deleted from the regulations on August 20, 1976 (41 FR 35184) following a U.S. Court of Appeals remand of the standard to OSHA (See Footnote 1).

Hazard review documents submitted by NIOSH to OSHA for each suspected carcinogen were instrumental in OSHA's designation of the fourteen chemicals. The hazard review documents summarized health effects of the suspected carcinogens including experimental animal and epidemiologic data. The information found in each document will be reviewed below.

The chemicals are defined in the regulations in terms of Chemical Abstracts Service Registry Numbers (CAS numbers).[8] Exhibit 1-5 lists the CAS numbers corresponding to each chemical name and the section in the Code of Federal Regulations which defines each chemical.

The designation of twelve of the chemicals is derived from a list of carcinogens prepared by the American Conference of Government Industrial Hygienists (ACGIH). OSHA selected all but one of the substances listed by ACGIH "in order to take advantage of the work and judgment of that group".[9] OSHA did not designate dimethyl sulfate even though it was on the ACGIH list because documentation of its carcinogenicity was inadequate.[10]

In addition to the chemicals on the ACGIH list, OSHA designated alpha-napthylamine because:

(1) alpha-napthylamine had frequently been found, in industrial experience and in epidemiologic studies, to be carcinogenic, and

(2) experimental animal studies demonstrated alpha-napthylamine's independent carcinogenicity.

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[8] For one chemical, 3,3'-Dichlorobenzidine (DCB), OSHA designated its salts in addition to the substance classified under the Chemical Abstracts Service Registry Number.

[9] Preamble to Occupational Safety and Health Standards for Carcinogens, 39 FR 3756, January 29, 1974.

[10] *Ibid*.

In its designation of the carcinogens, OSHA excluded solid or liquid mixtures containing less than specified percentages of the listed substances. "The exclusion of the mixtures rests, not on a finding that the mixtures are non-carcinogenic, but rather on a decision not to regulate them at this time" (39 FR 3759). OSHA decided not to regulate mixtures in order "to avoid substantial obstruction, if not stoppage, of the use of many processes and products which are considered useful in industry and even in cancer research, and about which the record contains very little information" (39 FR 3759).

Mixtures of seven of the carcinogens containing less than 1 percent by weight or volume are excluded from the standards. Furthermore, solid or liquid mixtures containing less than 0.1 percent of six other designated carcinogens are excluded. The exclusionary percentage for mixtures of these six substances is 0.1 percent (rather than 1 percent) because "these substances are known to be potent human carcinogens". (39 FR 3759, see Exhibit 1-5).

EXHIBIT 1-5

Thirteen Carcinogens Designated as Toxic and Hazardous Substances Under Section 6(b) of the OSH Act

Chemical Name	CAS Number	29 CFR Section	Exclusionary Percentage for Mixtures
4-Aminodiphenyl (4-ADP)	92671	1910.1011(a)(1)	0.1
4-Nitrobiphenyl	92933	1910.1003(a)(1)	0.1
Alpha-Napthylamine (1-NA)	134327	1910.1004(a)(1)	1.0
Beta-Napthylamine (2-NA)	91598	1910.1009(a)(1)	0.1
Methyl Chloromethyl Ether	107302	1910.1006(a)(1)	0.1
3,3'-Dichlorobenzidine (DCB)[a]	91941	1910.1007(a)(1)	1.0
bis-Chloromethyl Ether (BCME)	542881	1910.1008(a)(1)	0.1
Benzidine	92875	1910.1010(a)(1)	0.1
Ethyleneimine (EI)	151564	1910.1012(a)(1)	1.0
Beta-Propiolactone (BPL)	57578	1910.1013(a)(1)	1.0
2-Acetylaminofluorene (2-AAF)	53963	1310.1014(a)(1)	1.0
4-Dimethylaminoazobenzene (DAB)	60117	1910.1015(a)(1)	1.0
N-Nitrosodimethylamine (DMN)	62759	1910.1016(a)(1)	1.0

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[a] OSHA's designation includes DCB salts.

Standards

The thirteen standards control exposures to carcinogens by isolating the areas of possible exposure with engineering controls and work practice requirements. For example, closed systems, mechanical seals, remote controls, local exhaust ventilation, laboratory hoods, and transfer point operations are used to achieve an isolated system. In addition, open vessel operations are banned (39 FR 3759). Some of the standards also require personal protective clothing and equipment to be used. No permissible exposure limits were prescribed for the thirteen carcinogens. OSHA preferred to prescribe engineering controls and work practice requirements because the Agency believed these methods "most effectively isolated employees from potential contamination" (39 FR 3759). OSHA considered the economic and technological feasibility of the standards prior to their adoption.

The next section will examine the health effects which OSHA cited as the rationale for designating and regulating each carcinogen. Any special regulatory provisions applicable to a particular chemical substance also will be discussed.

4-Aminodiphenyl (4-ADP). The designation of 4-Aminodiphenyl was based on accumulated experimental and epidemiologic evidence demonstrating that 4-ADP was the "most hazardous aromatic amine regarding carcinogenic potential" (39 FR 3756). 4-ADP was shown to induce bladder cancer in humans and to induce malignant tumors in rabbits and mice.

4-Nitrobiphenyl. In the hazard review documents, NIOSH demonstrated the structural similarity of 4-Nitrobiphenyl and 4-Aminodiphenyl. It documented experimental evidence for the in vivo formation of 4-Aminodiphenyl from 4-Nitrobiphenyl. NIOSH's review included epidemiologic investigations which showed the potential of 4-Aminodiphenyl to induce bladder cancer in humans. OSHA designated 4-Nitrobiphenyl as a carcinogen on the basis of this evidence, and on the possibility that cases of human urinary bladder cancer, attributed to only 4-Aminodiphenyl, might have been induced by exposure to 4-Nitrobiphenyl (39 FR 3757).

Alpha-Napthylamine (1-NA). Alpha-Napthylamine is readily metabolized to various derivatives, several of which have a demonstrated carcinogenic potential in experimental animals. In particular, one metabolite of 1-NA, N-Hydroxy-1-naphthylamine, possesses great carcinogenic potential. Epidemologic studies have failed to eliminate an active role for 1-NA as a human bladder carcinogen. For these reasons, OSHA designated 1-NA as a carcinogen and established health standards for it.

Beta-Napthylamine (2-NA). In designating beta-napthylamine, OSHA cited studies which demonstrated that 2-NA induced cancer of the urinary bladder in dogs, rhesus monkeys, and hamsters. In addition, studies showed that tumors were induced in other organs of rats and mice exposed to 2-NA. OSHA also considered epidemiologic investigations of worker populations exposed to 2-NA which "clearly demonstrated that this substance was carcinogenic in humans" (39 FR 3757).

OSHA excluded operations involving the destructive distillation of carbonaceous materials from the 1-NA and 2-NA regulations because these chemicals will be controlled in separate regulations as components of coke oven emissions (29 CFR 1910.1009(a)(3)).

Methyl Chloromethyl Ether. Designation of this chemical was based on experimental animal investigations involving chemically purified methyl chloromethyl ether which demonstrated that this substance possessed a carcinogenic potential. Additionally, epidemiologic investigations which strongly implicated methyl chloromethyl ether as a human carcinogen were cited by OSHA.

Unlike most of the other carcinogen standards, this standard did not include wash requirements for closed systems or transfer operation uses of the chemical. OSHA's rationale for this exclusion was that methyl chloromethyl ether was a volatile material which would not be present long enough for routine washing or showering to offer any significant protection for employees working in areas where volatile materials were present.

3,3'-Dichlorobenzidine (DCB). Controlled animal studies involving rats, mice, and hamsters showed DCB to be carcinogenic in animals. This evidence served as the basis for OSHA's determination that DCB was potentially carcinogenic in humans. Extrapolation of animal studies to humans was the sole designation criterion. The NIOSH hazard review document gave evidence that DCB was detected in the urine of workers receiving a minimum of exposure. However, the metabolism of DCB was unknown, so OSHA did not rely on this evidence in designating DCB as a carcinogen or in setting the standard.

Bis-Chloromethyl Ether (BCME). The NIOSH hazard review document cited investigations with experimental animals (mice and rats) which demonstrated that BCME was a "very hazardous carcinogenic substance." (39 FR 3757) These investigations included skin application and subcutaneous injection of BCME in experimental animals which resulted in malignant lesions at the site of application or injection and in malignant tumors of the lungs. In addition, studies showed that 1 ppm or 0.1 ppm of BCME in air induced lung cancer in mice and rats. OSHA concluded from these studies that employee exposure to BCME was extremely hazardous and, hence, designated BCME for regulation.

Benzidine. OSHA designated benzidine as a human carcinogen because experimental animal investigations involving rats, dogs, hamsters, and mice demonstrated the carcinogenicity of benzidine. Additionally, epidemiologic investigations of worker populations exposed to benzidine "clearly demonstrated that this substance and its salts (e.g., benzidine sulfate) were also carcinogenic in humans." (39 FR 3756) The epidemiologic studies showed that the incidence of urinary bladder cancer in workers exposed to benzidine greatly exceeded the incidence of this disease in the general population.

Although benzidine salts were shown to be carcinogenic in humans, they are not covered by the regulations. The Chemical Abstracts Service Registry Number (92875) used to define benzidine in the regulations does not include benzidine salts.

Ethyleneimine (EI). Ethyleneimine was designated by OSHA as a carcinogen because two, separate, controlled animal studies demonstrated its carcinogenic potential. OSHA extrapolated to humans the results of those studies and designated EI for regulation (39 FR 3757).

Beta-Propiolactone (BPL). The carcinogenicity of BPL was demonstrated in mice, rats and hamsters. The designation of BPL was based solely on these animal health effects because epidemiologic evidence demonstrating BPL to be carcinogenic for humans was not available (39 FR 3757).

2-Acetylaminofluorene (2-AAF). Experimental animal investigations involving rats, mice, rabbits, dogs, hamsters and fowl were cited by OSHA as evidence that 2-AAF was carcinogenic. These studies demonstrated that 2-AAF was metabolized in animals to form a more carcinogenic metabolite, N-hydroxy-2-AAF. Other studies showed that humans also metabolize 2-AAF to the same carcinogenic metabolite. Thus, OSHA concluded that 2-AAF was carcinogenic in humans (39 FR 3756).

4-Dimethylaminoazobenzene (DAB). DAB was designated by OSHA on the basis of numerous reports demonstrating DAB to be carcinogenic in rats, dogs, neonatal mice, and trout. OSHA believed DAB to be carcinogenic in humans because of the similarity in metabolism of DAB in dogs and humans (39 FR 3757).

N-Nitrosodimethylamine (DMN). OSHA cited experimental studies demonstrating the carcinogenicity of DMN in the liver, kidney, lungs and nasal area of the rat as instrumental in designating DMN as a human carcinogen. In addition, OSHA considered other experimental animal investigations demonstrating the carcinogenicity of DMN for the mouse, hamster, guinea pig, rabbit, and several species of fish.

DMN was the last of the chemicals regulated by OSHA in the group of thirteen carcinogens.

Vinyl Chloride

Basis for Designation

Vinyl chloride[11] was designated for regulation on the basis of experimental animal and human epidemiologic studies demonstrating its carcinogenic potential.

The carcinogenicity of vinyl chloride for rats, mice, and hamsters exposed by inhalation was documented in several studies and a dose-dependent relationship for induction of tumors in rats and mice was demonstrated. Exposure concentrations as low as 50 ppm vinyl chloride induced angiosarcoma of the liver in rats and mice.

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[11] Vinyl chloride means "vinyl chloride monomer" (29 CFR 1910.1017(b)(10)), "(chloroethane), Chemical Abstracts Service Registry Number 75014 or polyvinyl chloride" (29 CFR 1910.1017(a)). Polyvinyl chloride means "polyvinyl chloride homopolymer or copolymer before such is converted to a fabricated product" (29 CFR 1910.1017(b)(9)).

Epidemiological studies documented a significant number of confirmed cases of angiosarcoma of the liver among employees exposed to VC. Considering the extreme rarity of angiosarcoma of the liver in the U.S. adult male population, this "is compelling evidence that exposure of humans to vinyl chloride induces this tumor."[12] OSHA cited additional evidence of tumor induction in a variety of other organs, including lung, kidney, brain, skin, as well as non-malignant alterations, such as fibrosis and connective tissue deterioration in designating vinyl chloride for regulation. After considering these animal and human studies, OSHA concluded "that VC must be regarded as a human carcinogen, and the probable cause agent of angiosarcoma of the liver, and that exposure of employees to VC must be controlled." (39 FR 35891).

Standards

As with asbestos, a standard for occupational exposure to vinyl chloride was included in the initial promulgation of OSHA air contaminant standards under Section 6(a) of the OSH Act. (36 FR 10506, May 29, 1971). The standard was derived from a 1969 federal standard issued under the Walsh-Healy Public Contracts Act and established an exposure ceiling for VC of 500 parts per million.

Pursuant to section 6(c) of the OSH Act, an emergency temporary standard for vinyl chloride was established reducing the exposure ceiling to 50 ppm (39 FR 12342, April 5, 1974). OSHA cited the following reasons for establishing a more restrictive emergency standard:

(1) New studies showed that tumors were observed in animals exposed to VC at concentrations as low as 250 ppm. OSHA concluded on the basis of this experimental animal data that VC was carcinogenic in humans at the level of 250 ppm.

(2) Experimental results in rats, hamsters, rabbits, and dogs indicated that exposure to VC at concentrations of 50 ppm failed to induce tumors. OSHA concluded from this evidence that occupational exposure of employees to concentrations of 50 ppm or below throughout their working lifetime would be without detrimental health effects.

(3) The 50 ppm standard was "the lowest level that could be complied with immediately" (39 FR 12342).

OSHA promulgated a permanent standard for exposure to vinyl chloride on October 4, 1975 (39 FR 35890). This standard prohibited employee exposure to vinyl chloride at concentrations greater than 1 ppm averaged over any 8-hour period, prohibited employee exposure to VC at concentrations greater than 5 ppm averaged over any period not exceeding 15 minutes, and prohibited employee exposure to VC by direct contact with liquid vinyl chloride (29 CFR 1910.1017(c)). The standard was based on the demonstrated evidence of VC's carcinogenicity in three animal species and the substantial probability that

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[12] Preamble to the Standard for Exposure to Vinyl Chloride, 39 FR 35891, October 4, 1974.

VC had been the causal agent in cases of liver angiosarcoma found in workers. In setting the vinyl chloride standard, the overriding consideration was "the protection of employees, even those who may have regular exposures to VC throughout their working lives" (39 FR 35892). Except for feasibility considerations, OSHA would have limited employee exposure to VC to "no detectable level" because safe exposure levels for carcinogenic substances could not be scientifically determined (39 FR 35890).

Upon consideration of feasibility, OSHA determined that 1 ppm was the lowest standard the VC industry could achieve with new technology and work practices (39 FR 35892). Even a 1 ppm standard would be achievable, according to OSHA, only (39 FR 35890, emphasis added) "for most job classifications most of the time". Subsequent experience has demonstrated this to be accurate.

Inorganic Arsenic

Basis for Designation

Inorganic arsenic[13] was designated because OSHA determined that exposure to inorganic arsenic posed a cancer risk to workers. OSHA's determination was based on epidemiologic studies of arsenic-exposed workers which showed an excess risk of lung cancer among exposed workers, and indicated that excess cancer risk increased consistently with increasing degree and exposure to inorganic arsenic. In addition, the studies suggested that copper aceto-arsenite, sodium arsenite, and potassium arsenite might be causal agents for lymphatic cancer.[14] OSHA considered NIOSH's view that, "when all reports of occupational exposure to inorganic arsenic are considered together, NIOSH believes it undeniable that there have been carcinogenic effects which must be attributed to inorganic arsenic."[15]

It should be noted that there were no positive animal studies to confirm the epidemiological findings of excess respiratory cancer mortality among workers exposed to inorganic arsenic. Animals are so sensitive to arsenic that they die before cancers can arise. Thus, OSHA relied solely on epidemiological data to designate inorganic arsenic.

OSHA designated both trivalent arsenic (arsenite) and pentavalent arsenic (arsenate) for regulation. The distinction between trivalent and pentavalent arsenic is important because trivalent arsenic is more toxic to humans than pentavalent arsenic. Epidemiological studies clearly indicated that trivalent arsenic was an important factor in the observed excess mortality from lung cancer whereas the role of pentavalent arsenic in respiratory cancer was not so clearly defined. OSHA based the decision to designate pentavalent arsenic as a carcinogen on:

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[13] "'Inorganic Arsenic' means copper aceto-arsenite and all inorganic compounds containing arsenic except arsine, measured as arsenic (As)." (29 CFR 1910.1018(b)).

[14] Copper aceto-arsenite, sodium arsenite, and potassium arsenite are covered in the regulations under the definition of inorganic arsenic.

[15] Occupational Safety and Health Reporter, Volume 7, Number 50, May 11, 1978, p. 1855.

(1) Recommendations from the National Cancer Institute and NIOSH to regulate pentavalent arsenic;

(2) One epidemiological study which showed a substantial excess cancer mortality among workers exposed principally to pentavalent arsenicals;[16] and,

(3) The chemical similarities between pentavalent and trivalent arsenic, and the strong evidence that trivalent arsenic is a carcinogen.

Standards

OSHA adopted a consensus standard for "arsenic and its compounds" under Section 6(a) of the OSH Act on May 29, 1971 (36 FR 10466). This standard established threshold limit values of 500 ug/m^3 for arsenic, 150 ug/m^3 for lead arsenate, and 1000 ug/m^3 for calcium arsenate.[17]

A permanent standard for inorganic arsenic was promulgated on May 5, 1978 which limited employee exposure to 10 micrograms per cubic meter of air based on an 8-hour time-weighted-average (43 FR 19624) . This standard was based on the body of epidemiological evidence discussed above which indicated that inorganic arsenic was a human carcinogen.

OSHA chose the 10 ug/m^3 standard because it was the lowest feasible level for exposure to inorganic arsenic in terms of technological considerations. OSHA's policy for carcinogens was to assume that there was no safe level of exposure. As a result, a zero level of exposure would be ideal, except that technological feasibility must also be considered in regulating substances under Section 6(b) of the OSH Act. According to OSHA, 10 ug/m^3 represented the lowest level which could be achieved by using engineering and work practice controls in most copper smelters and other processes in which inorganic arsenic was used. The 10 ug/m^3 level would "minimize, to the maximum extent feasible, excess lung cancer deaths resulting from exposure to inorganic arsenic" (43 FR 19624).

OSHA also analyzed the economic impact of the standard on all affected industries including the copper smelting industry, the lead smelting industry, zinc smelters, and glass manufacturers. OSHA concluded that the 10 ug/m^3 standard would not present "overly-burdensome" costs of compliance to industry.

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[16] M. OH, B. Holder, H. Gordon, "Respiratory Cancer and Occupational Exposure to Arsenicals" Archives Environmental Health 29, 250-5 (1974).

[17] Arsenic, lead arsenate, and calcium arsenate are covered in the permanent regulations under the definition of inorganic arsenic.

Lead

Basis for Designation

Lead[18] was designated for regulation by OSHA because of medical and scientific evidence indicating lead adversely affected the health of workers in the lead industry. This evidence included epidemiological studies and experimental investigations. The adverse health effects associated with exposure to lead and cited by OSHA as rationale for lead's designation, included damage to four basic human systems: neurological, renal, reproductive and heme synthesis (which is responsible for oxygen transport in living systems).

Standards

A national consensus standard of the American National Standards Institute was adopted by OSHA for lead pursuant to Section 6(a) of the OSH Act in 1971. The permissible exposure limit was 200 ug/m^3 as determined by an 8-hour time-weighted-average. When OSHA originally adopted the consensus standard, no rationale was provided for the level selected.

OSHA promulgated a permanent lead standard on November 14, 1978 (43 FR 52952). The permissible exposure limit (PEL) set by this standard was 50 micrograms of lead per cubic meter of air (50 ug/m^3) averaged over an 8-hour period. In addition, the standard contained a formula to calculate permissible exposure limits for exposures longer than 8-hours; this formula lowered the PEL as time exposed increased. An action level of 30 ug/m^3 (time-weighted-average based on an 8-hour work-day) was also established.

The decision to establish the PEL was based on considerations of health effects associated wih exposure to lead, feasibility issues, and the correlation of airborne concentrations of lead with blood lead levels that were associated with adverse effects and symptoms of lead exposure.[19]

In evaluating the adverse health effects associated with exposure to lead, OSHA decided that "early stages of the disease process characterized by central nervous system symptoms, behavioral changes, peripheral nerve damage, anemia, reduced kidney function, and adverse reproductive effects represent material impairment of the worker and should be prevented in order to eliminate further development of disabling disease and death." (43 FR 52963). Thus, OSHA developed the permissible exposure limit to protect workers from "the earliest indications of the onset of disease," as well as from "the most overt symptoms of illness." OSHA intended this standard to prevent occupational disease resulting from both acute and prolonged or chronic exposure to lead. The standard also was promulgated "to guard against the onset, progression, or severity of chronic degenerative diseases of aging workers." Furthermore, the PEL was based on providing a degree of protection to "the more susceptible, as well as the more robust members of the exposed group (43 FR 52963)."

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[18] "'Lead' means metallic lead, all inorganic lead compounds, and organic lead soaps. Excluded from this definition are all other organic lead compounds" (29 CFR 1910.1025(b)).

[19] Preamble to Occupational Exposure to Lead Final Standard, 43 FR 52963, November 14, 1978.

In order to establish a permissible exposure limit, OSHA estimated the blood lead levels associated with adverse effects of lead exposure and correlated these blood lead levels wih airborne concentrations of lead. OSHA utilized a physiological model to calculate the predicted blood lead distributions at various air lead levels.

OSHA determined that to protect employees from "material impairment of health or functional capacity . . . for the period of their working lives" (as required by Section 6(b)(5) of the OSH Act), the mean blood lead level of lead workers should be kept below 40 ug/100g. The provisions of this lead standard were designed to achieve an airborne lead-level which would limit blood lead (PbB) levels to a mean blood level of 40 ug/100g. A PEL of 50 ug/^{3} would not maintain the blood lead levels of all occupationally exposed workers below 40 ug/100g. However, this PEL would substantially reduce the number of exposed lead workers who would have blood lead levels above 40 ug/100g at any one time. It was this improvement that OSHA cited as the rationale for the PEL.

OSHA based the action level standard of 30 ug/m^3 on evidence which indicated that blood lead levels of workers (men and women) who wished to plan pregnancies should be maintained at less than 30 ug/100g during this period (43 FR 52963).

In setting the PEL and the action level, OSHA considered the feasibility of the lead standard which must be met by engineering controls, work practices, and personal protective equipment. In evaluating whether compliance was feasible, OSHA identified affected industries and investigated potential compliance methods including the available technology in those industries. Furthermore, OSHA estimated the length of time necessary to implement the technology required and took into account the firm's need to plan, construct, and test their efforts. OSHA also assured that the standard reflected compliance time periods which would enable firms in each industry to comply with the standard "without serious economic repercussions to the industry as a whole" (43 FR 52978).

OSHA identified primary and secondary smelters, pigment manufacturers, brass/bronze foundries and battery manufacturers as the industries with the greatest potential difficulties in complying with engineering controls. The 50 ug/m^3 exposure limit was the lowest level for which there was evidence of feasibility for these industries. OSHA stated that the 50 ug/m^3 PEL was the level which represented the "best intersection between maximization of health benefits and feasibility" (43 FR 52963).

Benzene

Basis for Designation

Benzene[20] was designated on the basis of scientific evidence which established that employee exposure to benzene presented a cancer hazard. Benzene was shown to attack the hematopoietic (blood-forming) systems and the bone marrow. Adverse hematopoietic effects of benzene including leukemia were documented in a variety of industries and occupations such as the rubber, shoe, rotogravure, painting, chemical processing, and can manufacturing industries. The types of studies cited by OSHA were single human case reports, cross-sectional human studies, retrospective studies of morbidity and mortality among a defined cohort of workers industrially exposed to benzene, and experimental demonstrations of marrow toxicity in animals exposed to benzene.

A NIOSH report cited by OSHA in the designation of benzene for regulation stated:

> NIOSH considers the accumulated evidence from clinical as well as epidemiologic data to be conclusive at this time that benzene is leukemogenic. Because it causes progressive, malignant disease of the blood-forming organs, NIOSH recommends, that for regulatory purposes, benzene can be considered carcinogenic in man.[21]

After considering all the scientific/medical evidence available, OSHA concluded that benzene exposure was causally related to the induction of leukemia, various cytopenias (decreased levels of a formed element in the circulating blood), aplastic anemia (a non-functioning bone marrow), and chromosomal aberrations. To minimize these worker health risks resulting from chronic exposure to low levels of benzene, OSHA designated benzene for regulation.

Standards

OSHA adopted the benzene consensus standard of the American National Standards Institute in 1971 under the authority of Section 6(a) of the OSH Act. This standard prescribed an 8-hour time-weighted-average of 10 ppm with a ceiling concentration of 25 ppm, and allowed excursions above the ceiling to a maximum peak concentration of 50 ppm for 10 minutes in any 8-hour work period. This standard was set to protect against adverse health effects of benzene, including blood changes and aplastic anemia, but not including leukemogenic effects.

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[20] "'Benzene' (C_6H_6) (CAS Registry No. 00071432) means solid, liquefied or gaseous benzene. It includes mixtures of liquids containing benzene and the vapors released by these liquids" (29 CFR 1910.1028(b)).

[21] NIOSH Criteria Document for Occupational Exposure to Benzene, 1976.

NIOSH submitted to OSHA a criteria document in August 1976 which concluded that benzene was a leukemogen, and recommended that "no worker be exposed to benzene in excess of 1 ppm in air." NIOSH acknowledged that no "safe" level for benzene exposure could be established.

In response to the criteria, OSHA issued an emergency temporary standard for occupational exposure to benzene in May 1977 (42 FR 22516), under the authority of Section 6(c) of the Act. A limit of 1 ppm benzene in air for an 8-hour time-weighted-average was included. This standard never officially went into effect because of legal challenges filed both in the Court of Appeals for the District of Columbia (Industrial Union, AFL-CIO v. Bingham, No. 77-1395) and in the Court of Appeals for the Fifth Circuit (API v. OSHA, No. 77-1516).

A final permanent benzene standard was promulgated on February 10, 1978 (43 FR 5918) and invalidated by the Supreme Court in July 1980.[22] This standard limited employee exposure to 1 ppm as an 8-hour time-weighted-average concentration with a ceiling level of 5 ppm for any 15 minute period during the 8-hour day. The standard also prescribed limits on eye and skin contact with benzene. The focus of the benzene standard was on minimizing worker risk resulting from chronic exposure to low levels of benzene.

OSHA selected the 1 ppm exposure level for the benzene standard because it was the lowest feasible level. It was OSHA's view that "once the carcinogenicity of a substance has been established qualitatively, any exposure must be considered to be attended by risk when considering any given population" (43 FR 5932). Thus, OSHA prescribed that the permissible exposure to benzene be reduced to the lowest feasible level.

To determine the lowest feasible level, OSHA evaluated the technological feasibility and the economic impact of the benzene standard on affected industries. Compliance costs for petroleum refineries, coke plants, petrochemical facilities, bulk terminals, oil and gas industries, transportation operations, and rubber products manufacturers were assessed by OSHA. From this study of compliance costs, OSHA determined that the 1 ppm standard was economically feasible.

Coke Oven Emissions

Basis for Designation

OSHA designated coke oven emissions[23] for regulation primarily because of evidence indicating that coke oven emissions played a causal role in the induction of lung cancer and genito-urinary tract cancer in exposed populations. This evidence included epidemiological surveys, animal studies, and chemical analyses of coke oven emissions.

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[22] The Supreme Court Justices failed to agree on a rationale for invalidating the standard. Industrial Union, AFL-CIO v. American Petroleum Institute, 48 USLW 5022, 1980.

[23] "'Coke' oven emissions mean the benzene-soluble fraction of total particulate matter present during the destructive distillation or carbonization of coal for the production of coke" (29 CFR 1910.1029, Appendix A).

Coke oven emissions are a complex mixture of particulates, vapors, and gases, in which multiple carcinogens and cocarcinogens have been identified. The chemicals found in coke oven emissions which are generally recognized as carcinogens are:

- Alpha-Napthylamine,[24]
- Beta-Napthylamine,[24]
- Benzo(b) fluoranthene,
- Benzo(j) fluoranthene,
- Benzo(a) pyrene,
- Benzo(b) anthracene
- Chrysene,
- Anthracene,
- Phenanthrene,
- Acridine, and
- Pyrene.

Agents known to enhance the effect of chemical carcinogens especially on the respiratory tract were also identified in coke oven emissions. No one substance in coke oven emissions was selected for regulation "because neither the manner in which such substances interact nor the specific causative agent had been identified with regard to the multiple types of cancer resulting from exposure to coke oven emissions." (41 FR 46745).

In designating coke oven emissions for regulation, OSHA also cited observations of animals and of human populations which demonstrated that skin tumors could be induced by constituents of coke oven emissions. This evidence was related to increased skin cancer mortality in coke oven workers. Finally, OSHA considered epidemiological studies which showed an elevated risk of non-malignant respiratory diseases such as bronchitis and emphysema in coke oven workers.

Standards

Standards limiting worker exposure to coke oven emissions first were adopted by OSHA under Section 6(a) of the OSH Act as established Federal standards. The OSHA standard set a coal tar pitch volatile (defined as the benzene soluable fraction and listing certain carcinogenic components namely anthracene, benzo(a)pyrene, phenanthrene, acridine, chrysene, and pyrene)[25] threshold limit value of $200 ug/m^3$. No rationale was provided by OSHA for selecting this level.

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[24] Alpha-napthylamine and beta-napthylamine were regulated by OSHA in the group of thirteen carcinogens, but the regulations excluded coke oven emissions. Both substances are covered under the permanent coke oven emissions standard.

The permanent coke oven emission standard was promulgated on October 22, 1976 (41 FR 46742). This standard established a permissible exposure limit (PEL) of 150 micrograms per cubic meter of air determined as an 8-hour average. The criteria used to determine this standard included the health effects data cited above and the technological and economic feasibility of the PEL.

In evaluating the technological and economic feasibility, OSHA focused on the steel industry because it was the major industry affected by the coke oven standard. OSHA cited, as indicative of the minimal economic impact and the technological feasibility of the standard, the fact that none of the steel industry spokespersons testified that the proposed standard for coke oven emissions would "imperil the existence" of the U.S. coke industry (41 FR 46742).

As with the other carcinogens regulated by OSHA, no safe level of exposure to coke oven emissions was known. Thus, the PEL was set as restrictive as technological and economic feasibility considerations allowed.

Cotton Dust

Basis for Designation

OSHA's designation of cotton dust[26] for regulation was based on epidemiological and clinical evidence that cotton dust produced adverse health effects among cotton workers. These adverse health effects included acute effects, such as depression of pulmonary function indicators, chest-tightness, shortness of breath and coughing, and chronic obstructive pulmonary disease. Byssinosis is a respiratory disease specifically attributable to the action of cotton dust on respiratory passages. Byssinosis causes health effects ranging from acute to chronic and from reversible to disabling, which have been "conclusively shown" to be causally related to exposure to cotton dust. (43 FR 27342). Thus, OSHA designated cotton dust for regulation to reduce the risk of cotton dust-induced respiratory diseases in workers.

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[25] These compounds are covered by the present standard.

[26] "'Cotton dust' means dust present in the air during the handling or processing of cotton, which may contain a mixture of many substances including ground-up plant matter, fiber, bacteria, fungi, soil, pesticides, non-cotton plant matter and other contaminants which may have accumulated with the cotton during the growing, harvesting and subsequent processing or storage periods. Any dust present during the handling and processing of cotton through the weaving or knitting of fabrics, and dust present in other operating or manufacturing processes using new or waste cotton fibers or cotton fiber by-products from textile mills are considered cotton dust" (29 CFR 1910.1043(b))).

OSHA designated the broadly defined heterogeneous mixture of cotton dust for regulation because the active agent or agents in cotton dust have not been identified. By broadly defining cotton dust, OSHA assured that the causative agents contained in the cotton dust mixture would be covered by the regulations.

Standards

OSHA adopted a standard of 1000 ug/m³ for "cotton dust (raw)" under Section 6(a) of the OSH Act in 1971. This standard originally was an established Federal standard under the Walsh-Healy Public Contracts Act.

OSHA adopted a permanent cotton dust standard on June 23, 1978 (43 FR 27350). The permissible exposure limit in the standard varies according to the type of industry as displayed in Exhibit 1-6.

The textile industry standard was based primarily on an epidemiological study which evaluated the prevalence of byssinosis in the United States textile industry. Approximately 3,000 workers employed in 8 cotton and cotton-synthetic blend mills, control synthetic mills and wool mills were investigated. The study demonstrated a strong linear association between the prevalence of byssinosis and the concentration of lint-free respirable dust.

The NIOSH Cotton Dust Criteria Document prepared in September 1974 recommended to OSHA that "no environmental limit of cotton dust will prevent all adverse effects on workers health". Recognizing the absence of any known "safe level of exposure" to cotton dust, OSHA set the permissible exposure limit (PEL) of 200 ug/m³ for the textile industry on the basis of feasibility considerations. OSHA concluded that "on the basis of all the currently available evidence, 200 ug/m³ of respirable cotton dust appears to represent the lowest possible level." (43 FR 27358). The epidemiological data indicated that a 200 ug/m³ PEL would result in a prevalence of byssinosis of 12.7 percent, which OSHA considered "to provide substantial protection for employees exposed to cotton dust" (43 FR 27358). OSHA considered setting the PEL at 100 ug/m³, but studies indicated that a level below 200 ug/m³ would be difficult to implement because of interference from background dust levels.

A higher exposure limit was established for special cases of slashing or weaving in the textile industry because a limit of 750 ug/m³ "provides weavers as safe an environment as their co-workers in other textile operations exposed to 200 ug/m³." (43 FR 27360). This conclusion was based on epidemiological data which showed a separate dose-response relationship for weavers. In addition, the dust in the atmosphere of a typical weaving room has been demonstrated to be composed primarily of sizing materials which dilute the cotton dust in the environment. Finally, OSHA cited evidence that engineering dust controls in weaving might not be feasible even with massive expenditures by industry.

OSHA established an exposure limit of 500 ug/m^3 for non-textile industries without the aid of quantitative dose-response data as was available for establishing the PEL in the textile industry. OSHA instead relied on evidence which suggested that cotton dust affected workers in a similar manner wherever cotton dust was generated. Citing the dose-response data for the textile industry, OSHA determined that cotton dust levels in non-textile industries also posed health risks, and set the 500 ug/m^3 PEL as the lowest feasible level.

EXHIBIT 1-6

Cotton Dust Standard a/

Type of Industry	Permissible Exposure Level (over 8-hour work shift)
Textile	200 ug/m^3
Textile (Slashing and Weaving)	750 ug/m^3
Non-textile	500 ug/m^3

In the development of these three cotton dust standards, OSHA evaluated the economic and technological feasibility of each standard. Evidence demonstrated that in textile and non-textile industries, modification and adaptation of existing dust control systems would permit compliance with the standards in the vast majority of workplaces. In the assessment of economic feasibility, OSHA conducted a thorough study of the economic impacts on affected industries. OSHA concluded from this study that the cotton dust standards were economically feasible and that the regulated industries would be able to survive the cost of compliance.

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a/ The standard applies to lint-free respirable cotton dust which is defined in the regulations as "particles of cotton dust of approximately 15 microns or less aerodynamic equivalent diameter" (29 CFR 1910.1043(b)).

Cotton Dust in Cotton Gins

Basis for Designation

The designation of cotton dust[27] in cotton gins was based on OSHA's determination that employee exposure is associated with a high prevalence of acute respiratory dysfunction. The previous section of this paper concerning the general cotton dust standard describes these adverse health effects in detail. Adverse health effects associated with cotton dust in cotton gins can be expected to be the same as adverse health effects associated with dust generated at all other stages of cotton processing. Evidence indicates that the physiological response of cotton gin workers does not differ significantly from the response of other workers handling cotton (43 FR 27420). Furthermore, cotton dust generated during ginning contains the same substances as cotton dust generated at all other stages of cotton processing.

OSHA promulgated a separate standard specifically for cotton dust in cotton gins because of the unique characteristics of cotton ginning which necessitated different treatment from other segments of the cotton industry. For example, the pattern of exposure to cotton dust in gins is different from the pattern in the rest of the cotton industry. Workers in cotton gins are exposed to cotton dust only for brief, intermittent periods, rather than long, year-round exposure. No evidence exists of chronic respiratory disease among gin workers exposed to current levels of dust in U.S. gins. Thus, OSHA decided to establish a standard specifically for the ginning segment of the cotton industry.

Standards

The final standard for cotton dust in cotton gins did not establish permissible exposure limits as were established for other segments of the cotton industry.[28] Instead, OSHA adopted work practice controls and respiratory controls including medical surveillance and employee education. OSHA concluded that work practice and respiratory controls would provide "an acceptable margin of safety for ginning employees" (43 FR 27423). This standard was vacated and remanded to OSHA by the Fifth Circuit Court of Appeals.

OSHA considered the economic and technological feasibility of this standard prior to its promulgation. A study of the standard's economic impact on affected industries was conducted and the costs of compliance estimated. The study indicated that application of the 200 mg/m^3 permissible exposure limit (the PEL for the rest of the cotton industry) to the cotton ginning industry would have a "momentous impact." (43 FR 27418). However, the study concluded that the work practice controls and respiratory controls required by the cotton dust standard for cotton gins would be economically and technologically feasible.

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[27] "'Cotton dust' means dust present in the air during the handling or processing of cotton which may contain a mixture of many substances including ground-up plant matter, fiber, bacteria, fungi, soil, pesticides, non-cotton plant matter, and other contaminants which may have accumulated with the cotton during the growing, harvesting, and subsequent processing or storage periods" (29 CFR 1910.1046(b)).

[28] 43 FR 27418 June 23, 1978.

1,2-Dibromo-3-chloropropane (DBCP)

Basis for Designation

OSHA established a standard for occupational exposure to DBCP[23] on the basis of scientific evidence that employee exposure to DBCP presented a hazard of cancer and sterility. Results of animal studies indicated DBCP to be a potent carcinogen in two sexes of two mammalian species at two dose levels. Additionally, DBCP caused positive results in microbial assays designed to detect chemicals capable of mutagenesis.

The conclusion that DBCP posed a sterility hazard was based on animal studies demonstrating that oral dosages of DBCP induced degeneration of testicular tissue, reduced sperm count and initiated abnormal sperm cell development. Furthermore, these testicular effects were confirmed in humans. Recent studies have indicated that a large number of male employees exposed to low levels of DBCP in the manufacture and formulation of pesticides suffer from sterility and infertility. On the basis of this evidence, OSHA concluded that DBCP had "proven carcinogenic and sterilant potential" (43 FR 11516), and thus, should be regulated in the workplace.

Standards

Based on a determination that employee exposure to DBCP presented a "grave danger" of sterility as well as cancer, OSHA published an emergency temporary standard on September 9, 1977 (43 FR 45536) regulating DBCP exposure in the workplace. Issued under the authority of Section 6(c) of the OSH Act, this emergency standard established an 8-hour time weighted average PEL of 10 parts DBCP per billion parts of air, with a permissible ceiling of 50 ppb as averaged over any 15 minute period in the workplace.

The final permanent DBCP standard was promulgated on March 17, 1978 (43 FR 11514). The standard limits employee exposure to DBCP to 1 part DBCP per billion parts of air (1 ppb) in an 8-hour time-weighted-average concentration. The standard also prohibits eye and skin contact with DBCP. The bases for the final standard were human and animal data demonstrating that DBCP causes sterility and animal data indicating that exposure to DBCP presents a cancer hazard to workers. "OSHA maintains that a substance which causes cancer in animals must be considered as posing a carcinogenic risk to workers" (43 FR 11520).

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[23] "'DBCP' means 1,2-dibromo-3-chloropropane, Chemical Abstracts Service Registry Number 96-12-8, and includes all forms of DBCP" (29 CFR 1910.1044(b)).

The 1 ppb concentration level represented the lowest exposure level achievable using present technology. Since there were no dose-response data for human exposures to DBCP, OSHA assumed that any level of exposure to DBCP posed a carcinogenic risk to exposed individuals. In addition, there was evidence that DBCP induced sterility and infertility in workers exposed to 40 to 430 ppb DBCP. OSHA decided that "adequate epidemiologic data does not exist which provides sufficient information to accurately predict a 'safe' or 'no effect' level, assuming one exists, with respect to the sterilant effects of DBCP." (43 FR 11520). Taking into consideration the "nature of the hazards of DBCP exposure and the inability to determine an exposure level that will eliminate the risk of cancer and sterility", OSHA set the PEL for DBCP at the lowest level technologically feasible.

To assess the feasibility of the DBCP standard, OSHA considered (1) the levels of DBCP exposure attainable using existing controls; (2) the sophistication of existing control methodologies; (3) the economic incentives for continued DBCP production, including the costs of compliance, the inelasticity of demand, the limited scale of production, and the possible changes in market structure with respect to DBCP; and (4) the relative sophistication of the companies producing DBCP with respect to control technology. In light of these considerations, OSHA determined the 1 ppb PEL to be technologically and economically feasibile (43 FR 11521).

The DBCP standard does not apply to exposures which result solely from the application and use of DBCP as a pesticide. OSHA believes the control of DBCP as a pesticide by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act provides "an effective approach to protecting all workers against the hazards of exposure to DBCP" (43 FR 11522).[30]

Acrylonitrile

Basis for Designation

Acrylonitrile (AN)[31] was controlled by OSHA because of laboratory and epidemiological data indicating that exposure to AN presented a cancer hazard to workers. Experimental studies showed excess incidences of tumor formulation in AN-exposed animals and epidemiological data indicated excess cancer among workers exposed to AN. Moreover, AN was shown to be capable of inducing mutations in animals.

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[30] EPA issued a Notice of Intent to Cancel for DBCP on October 29, 1979 (44 FR 63135). A Notice of Intent to Cancel gives the public an opportunity to request a hearing to review the cancellation of the registration of a pesticide. A hearing for DBCP was scheduled to begin in September 1980, but was delayed until further notice. EPA requested the delay to negotiate an agreement with registrants and environmental groups. At the time of the cancellation notice, EPA also suspended the use of DBCP until the cancellation issue is resolved.

[31] "'Acrylonitrile' or 'AN' means acrylonitrile monomer, chemical formula $CH_2 = CHCN$" (29 CFR 1910.1045(b)).

OSHA cited, as evidence of AN's health risks, the results of the National Cancer Institute's carcinogenicity testing program which "recognized acrylonitrile as carcinogenic to experimental animals." Additionally, NIOSH concluded that the results from experimental animal studies "strongly suggest that AN is carcinogenic in man." OSHA also cited results of studies conducted by the International Agency for Cancer Research (IARC) of the World Health Organization and the Food and Drug Administration in the determination that AN is a human carcinogen.

Liquid AN[32] also was specified for regulation to assure that all intermediate products of the AN polymerization process were covered by the standard.

Standards

Occupational exposure to AN was limited by OSHA to an 8-hour time-weighted average of 20 ppm in 1971, under Section 6(a) of the OSH Act. This 20 ppm standard was not based on carcinogenicity of AN, but was based on its high acute toxicity and its similarity to hydrogen cyanide.

On January 17, 1978, OSHA issued an emergency temporary acrylonitrile standard (43 FR 2586). This emergency standard was based on OSHA's determination that "exposure to AN posed a grave danger to humans because of AN's carcinogenic potential." The standard established a PEL of 2 ppm as an 8-hour time-weighted-average with a ceiling limit of 10 ppm (15-minute average).

The final AN standard was promulgated on October 3, 1978 (43 FR 45762). It adopted the emergency standard and set the PEL at 2 ppm (8-hour average), with a ceiling level of 10 ppm (15-minute average). In addition, the final standard established an action level of 1 ppm as an 8-hour time-weighted-average. As discussed above, the basis for this standard was OSHA's determination that AN posed carcinogenic risks to workers. OSHA believed that standards for substances which had been found to pose cancer risks to workers must assure "maximum benefit (i.e., prevention of serious illness or death) constrained only by the limits of feasibility" (43 FR 45790). Accordingly, the PEL represented the lowest level which OSHA believed to be generally achievable through the use of engineering controls, work practices and respirators. The standard was based upon analysis of the affected industries taken as a whole because a facility-by-facility approach would have been extremely difficult to implement.

In accordance with Section 6(b)(5) of the OSH Act, OSHA considered the economic and technological feasibility of the AN standard. The determination that the PEL was technologically feasibile was based on nearly universal agreement by the affected companies that existing technology and modifications of existing technology would be capable of reducing exposures in most operations to below the PEL. To assess the economic feasibility of the AN standard, the costs of compliance were estimated and the impacts on critical materials, market structure, productivity, employment, energy, and prices were examined for the AN industry. The results of the study indicated that the AN standard was economically feasible for the affected industries.

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[32] "Liquid AN' means AN monomer in liquid form, and liquid or semi-liquid polymer intermediates, including slurries, suspensions, emulsions, and solutions, produced during the polymerization of AN" (29 CFR 1910.1045(b)).

Beryllium

Basis for Designation

The designation of beryllium[33] for regulation under the OSH Act was based on epidemiological and clinical evidence of acute and chronic health effects in workers exposed to beryllium, and on experimental animal data showing that beryllium compounds produced cancer in laboratory animals. Acute health effecs of beryllium cited by OSHA included effects on the eye and skin area and respiratory effects. Chronic health effects included pneumonitis, systemic disease, and pulmonary dysfunction.

Standards

OSHA initially adopted the American National Standards Institute's beryllium standard in accordance with Section 6(a) of the OSH Act. This standard prescribed an 8-hour time-weighted-average of 2.0 ug/m^3 with a ceiling concentration of 5.0 ug/m^3. In addition, the standard allowed a peak concentration above the acceptable ceiling concentration for an 8-hour shift of 25 ug/m^3, for a maximum duration of 30 minutes. This standard was based on experimental animal data and on analogy with industrial air limits for such toxic heavy metals as mercury, cadmium, and thallium; the ceiling was based on actual dose/response data taken in-plant.

OSHA proposed a beryllium standard on October 17, 1975 (40 FR 48814) reducing the permissible employee exposure for an 8-hour time-weighted-average concentration to 1.0 ug/m^3. The proposal also set a 5 ug/m^3 ceiling limit for exposures to airborne concentrations of beryllium (15-minute averaging time), eliminated the peak concentration level of 25 ug/m^3, and proposed a dermal exposure limit.

In developing this proposed standard, OSHA considered recommendations contained in the NIOSH document, "Occupational Exposure to Beryllium (Criteria for a Recommended Standard)"[34] and the Atomic Energy Commission's Control

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[33] "'Beryllium' means elemental beryllium and compounds and alloys of beryllium (as elemental beryllium) that may be released into the place of employment as particulate matter or that may be present in the place of employment in bulk forms" (29 CFR 1910.1026(b)).

[34] NIOSH, Washington, D.C., (PHS, HSMHA), 1972, (HSM 72-10268).

Requirements for Beryllium, as well as almost everything else published on the subject.

OSHA decided to lower the PEL to 1.0 ug/m^3 because of evidence indicating that beryllium exposures in most cases were being controlled "to well below the current standard" of 2.0 ug/m^3 (40 FR 48818, October 17, 1975). The 1.0 ug/m^3 proposed standard represented a compromise "between the best medical and scientific evidence on the one hand and practical consideration of technological and economic feasibility on the other." (40 FR 48818) OSHA included a dermal and eye exposure limit for bulk forms of beryllium[15] in the proposed standard because of human and animal studies demonstrating that the "soluble salts of berylium" upon contact, produced adverse effects to the skin and eye area.

To date, no final beryllium standard has been promulgated by OSHA. The agency is determining whether the standard is needed or not.[16]

THE OSHA CANCER POLICY

OSHA promulgated a set of regulations on January 22, 1980 (45 FR 5002) for the identification, classification, and regulation of toxic substances for which there is reported to be evidence of carcinogenic potential in humans. These regulations are referred to as "The OSHA Cancer Policy" and were issued as Part 1990 of Title 29 of the Code of Federal Regulations.

The announced purpose of the regulations are:

(1) to provide an orderly, comprehensive, consistent, and scientifically feasible system for regulatory actions to reduce or prevent worker exposures to potential carcinogens;

(2) to permit OSHA to regulate potential carcinogens in a timely manner;

(3) to present the factors OSHA will consider in setting priorities for the regulation of potential carcinogens; and

(4) "to carry out the intent of the [OSH] Act with respect to identification, classification, and regulation of potential occupational carcinogens" (29 FR 1990.102).

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[15] "'Bulk forms' means beryllium which is not airborne but which poses a dermal hazard to employees upon contact with, or penetration of the skin. Such forms include soluble beryllium, compounds or solid forms (i.e., crystals, chips, shavings, etc.) of soluble or insoluble beryllium which could penetrate the skin." (29 CFR 1910.1026(b)).

[16] Source: OSHA Staff.

Classification Provisions

The regulations classify potential occupational carcinogens into two categories depending on "the nature and extent of the available scientific evidence." The classification system clearly specifies the criteria OSHA will rely on when designating substances as carcinogenic and when establishing standards for them under the OSH Act.

Specifically, a substance is identified, classified, and regulated as a Category I Potential Carcinogen if the substance meets the definition of a potential occupational carcinogen[37] in: (i)humans, or (ii) in a single mammalian species in a long-term bioassay where the results are in concordance with some other scientifically evaluated evidence of a potential carcinogenic hazard or (iii) in a single mammalian species in an adequately conducted long-term bioassay, in appropriate circumstances." (29 CFR 1990.112(a)). Concordance is demonstrated by any of the following: "positive results from independant testing in the same or other species, positive results in short-term tests,[38] or induction of tumors at injection or implantation sites." (29 CFR 1990.112(a)).

Category II Potential Carcinogens include substances which: (1) "meet the criteria set forth in 1990.112(a) [for a Category I Potential Carcinogen], but the evidence is found to be only 'suggestive'" or (2) "meet the criteria set forth in 1990.112(a) in a single mammalian species without evidence of concordance" (29 CFR 1990.112(b)).

OSHA distinguished between Category I and Category II toxic substances to minimize the influence of "false positive" results on OSHA's decision-making process and to increase the degree of scientific confidence in positive results.

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[37] "Potential occupational carcinogen" means any substance, or combination or mixture of substances, which causes an increased incidence of benign and/or malignant neoplasms, or a substantial decrease in the latency period between exposure and onset of neoplasms in humans or in one or more experimental mammalian species as the result of any oral, respiratory or dermal exposure, or any other exposure which results in the induction of tumors at the site other than the site of administration. This definition also includes any substance which is metabolized into one or more potential occupational carcinogens by mammals. (29 CFR 1990.103).

[38] "'Positive results in short-term tests' means positive results in assays for two or more of the following types of effect: (1) the induction of DNA damage and/or repair; (2) mutagenesis in bacteria, yeast, neurospora or drosophila melanogaster; (3) mutagenesis in mammalian somatic cells; (4)mutagenesis in mammalian germinal cells; or (5) neoplastic transformation of mammalian cells in culture" (29 CFR 1990.103).

Priority Setting Provisions

The regulatory provisions are intended to establish a "flexible process for screening evidence on substances that may be potential occupational carcinogens and for setting priorities among such substances for full scientific evaluation and regulation as potential occupational carcinogens." (45 FR 5207).

The regulations require OSHA to establish two priority lists for regulating potential occupational carcinogens. Each list should include "approximately ten candidates for rulemaking." One list should be for Category I Potential Carcinogens while the other should include candidates for Category II Potential Carcinogens. The factors, specified by OSHA, to be considered when setting priorities include:

(1) "The estimated number of workers exposed;

(2) The estimated levels of human exposure;

(3) The levels of exposure to the substance which have been reported to cause an increased incidence of neoplasms in exposed humans, animals, or both;

(4) The extent to which regulatory action could reduce not only risks of contracting cancer but also other occupational and environmental health hazards;

(5) Whether the molecular structure of the substance is similar to the molecular structure of another substance which meets the definition of a potential occupational carcinogen;

(6) Whether there are substitutes that pose a lower risk of cancer or other serious human health problems, or available evidence otherwise suggests that the social and economic costs of regulation would be small; and

(7) OSHA will also consider its responsibilities for dealing with other health and safety hazards and will consider the actions being taken or planned by other governmental agencies in dealing with the same or similar health and safety hazards." (29 CFR 1190.132(b)).

Rulemaking Procedures

The OSHA Cancer Policy prescribes specific rulemaking procedures for occupational carcinogens. The required contents of proposed standards and emergency temporary standards for both categories of potential carcinogens are specified. This is to achieve consistency among future rulemakings for carcinogens.

General provisions for the use of animal and human data also are included in the OSHA Cancer Policy. These provisions review most of the scientific issues concerning carcinogens and establish general rules concerning the use of scientific information on carcinogenesis. In addition, Part 1990.146 lists the issues which may be considered in potential carcinogen rulemakings. The purpose of these sections is "to improve both the efficiency and specificity of individual rulemakings, ensure uniformity of treatment and avoid continual relitigation of issues already clearly resolved" (45 FR 5212).

Finally, the OSHA Cancer Policy presents two model standards for OSHA to follow in carcinogen rulemaking proceedings. These example standards include a permanent standard format and an emergency temporary standard format. OSHA explained that "the inclusion of model standards is expected to improve OSHA's ability to respond appropriately to scientific evidence concerning potential occupational carcinogens and thereby help transform the Cancer Policy into tangible employee protection" (45 FR 5218).

GENERIC HAZARD IDENTIFICATION AND LABELING

OSHA has proposed and subsequently withdrawn generic hazard identification and labeling standards for chemicals categorized as physical hazards, acute/subacute health hazards, and chronic health hazards.[33] The following review of the proposed standard is for information only.

There were four major provisions to the proposed rule. First, manufacturers or importers were required to evaluate all chemical substances and mixtures manufactured by or imported by them to determine if the materials are hazardous according to criteria specified in the standard. Second, containers of substances and mixtures determined to be hazardous were to be labeled before distribution in commerce. All labels were to include the CAS number, the common name of the container's contents (or the common names(s) of its hazardous constituent substance(s), in the case of mixtures), a signal word (e.g., "DANGER!", "WARNING!", or "CAUTION!"), a statement of hazards, precautionary statements, instructions in case of fire, spill, or leak, antidote information, and instructions for container handling and storage. Third, manufacturers and industrial users were required to provide employees with material safety data sheets to supplement the information on hazard warning labels. The data sheets were to include detailed information about the properties and handling of hazardous substances and mixtures, and were to be updated according to procedures specified in the proposed standard. Fourth, to enable workers to make their own hazard determinations and to evaluate their employer's determinations, manufacturers and importers were required to maintain hazard evaluation files containing references, studies, reports, and other documents used in hazard evaluation.

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[33] OSHA Proposed Rules On Hazard Identification, 46 FR 4412, January 16, 1981. Withdrawn February 12, 1981, 46 FR 12020.

The proposed hazard identification and labeling rule applied to substances and mixtures which fell into two general hazard categories. Category A included physical hazards and Category B included acute/subacute and chronic health hazards as displayed in Exhibit 1-7. Substances and mixtures, with the exceptions of nuclear material, food, and tobacco, which met the definition for one or more classes of hazards were to be covered by the proposed rule.[40]

To determine if substances and mixtures met the criteria of Category A or B, manufacturers and importers were required to evaluate scientific reports and other data according to the procedures presented in Appendicies A and B of the proposed rule. Mixtures were to be evaluated for hazards on the basis of their constituent substances unless hazard data concerning a mixture as a whole were available.[41]

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[40] Substances and mixtures used for scientific experimentation, chemical research, or product development were covered only by the hazard evaluation file requirements.

[41] According to OSHA's proposed rule, a mixture poses the hazards of its constituent substances if:

> (1) "The mixture contains a constituent substance in an amount of at least 0.1% (by weight) which is determined to be a carcinogen. . . ."
>
> (2) "Any of the constituent substances of the mixture in an amount of at least 1.0% (by weight) meet the definition for one or more Category A or Category B hazards. . ."

EXHIBIT 1-7

CRITERIA FOR HAZARD IDENTIFICATION AND LABELING (PROPOSED)

Category A: Physical Hazards	Definitions
Corrosive Material	• Causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. • Destroys rabbit skin in four hours (method described in 49 CFR 173, Appendix A, Department of Transportation).
Explosive Material	Causes a sudden, almost instantaneous release of pressure, gas and heat when subjected to sudden shock, pressure or high temperature.
Extremely Flammable Liquid	Has a flash point at or below 20°F (-6.7°C) as determined by closed cup methods.
Flammable Material:	
Flammable aerosol	Projects a flame longer than 18 inches when the valve is fully open or a flashback (a flame extending back to the valve) at any valve opening (see 16 CFR 1500.45 Consumer Product Safety Commission).
Flammable gas	At atmospheric temperature and pressure forms a flammable mixture with air when it is present in air at a concentration of 13 percent or less by volume, or the flammable range with air is wider than 12 percent, regardless of the lower limit.
Flammable liquid	Has a flash point above 20°F (-6.7°C) but below 100°F (37.8°C), except that this term does not include any liquid mixture that has one or more components with flash points at or above 100°F (37.8°C) which together make up 99 percent or more of its total volume.
Flammable solid	Causes fire through friction, absorption of moisture, spontaneous chemical change, or retained heat from manufacturing or processing or can be readily ignited and, when ignited, continues to burn vigorously and persistently after the source of ignition is removed. A material is considered a flammable solid if, when it is tested by the method described in 16 CFR 1500.44, (Consumer Product Safety Commission) it ignites and burns with a self sustained flame at a rate greater than one-tenth of an inch per second along its major axis.
Combustible Liquid	Has a flash point at or above 100°F (37.8°C) but below 200°F (93.3°C), except that this term does not include any liquid mixture that has one or more components with flash points at or above 200°F (93.3°C) which together make up 99 percent or more of its total volume.
Pyrophoric Material	Ignites spontaneously in dry or moist air at or below 130°F (54.4°C).
Strong Oxidizer	Ignites or promotes combustion in other materials, thereby causing fire either of itself or through the release of oxygen or other gases.

EXHIBIT 1-7

CRITERIA FOR HAZARD IDENTIFICATION AND LABELING (PROPOSED)
(Continued)

Category A: Physical Hazards	Definitions
Reactive Material	Undergoes a violent self-accelerating exothermic chemical reaction with common materials or by itself and includes a substance or mixture that falls within any of the following categories: (1) Organic peroxide. An organic compound that contains the bivalent -O-O- structure and which may be considered a structural derivative of hydrogen peroxide, in which one or both of the hydrogen atoms has been replaced by an organic radical. (2) Pressure-generating material. A substance or mixture which may spontaneously polymerize, with an increase in pressure, unless protected by the addition of an inhibitor, or by refrigeration or other thermal control; or which may decompose to release gas in its container. (3) Water-reactive material. A substance or mixture that reacts with water to release heat or a gas which is hazardous.
Compressed Gas	• A gas or mixture of gases having in a container an absolute pressure exceeding 40 pounds per square inch at 70°F (21.1°C); or exceeding 104 pounds per square inch at 130°F (54.4°C), regardless of the pressure at 70°F (21.1°C). • A flammable liquid having a vapor pressure exceeding 40 pounds per square inch absolute pressure at 100°F (37.8°C), as determined by the American Standard Method of Test for Vapor Pressure of Petroleum Products (Reid Method), Z11:44-1973 (ASTM D 323-72). • The contents of a self-pressurized container.
Category B: Health Hazards	
(1) Acute/Subacute Health Hazards	
Highly Toxic Material	• Rat oral LD_{50} equal to or less than 50 mg per kg body weight. • Rabbit dermal LD_{50} equal to or less than 200 mg per kg body weight. • Rat inhalation LC_{50} equal to or less than 200 ppm (gas or vapor). • Rat inhalation LC_{50} equal to or less than 2 mg per liter (mist, fume or dust).
Toxic Material	• Rat oral LD_{50} between 50 and 500 mg per kg body weight. • Rabbit dermal LD_{50} between 200 and 1000 mg per kg body weight. • Rat inhalation LC_{50} between 2 and 20 mg per liter (mist, fume or dust).
Irritant:	Not a corrosive, which on immediate, prolonged or repeated contact with living human or mammalian tissue induces the immediate or delayed onset of an acute, subacute or chronic local inflammatory response in the skin, eyes, or mucous membranes by chemical action.
Skin	Receives score of 5 or more (method described in 16 CFR 1500.41, Consumer Product Safety Commission).
Eye	Positive result (method described in 16 CFR 1500.42, Consumer Product Safety Commission).

EXHIBIT 1-7

CRITERIA FOR HAZARD IDENTIFICATION AND LABELING(PROPOSED)
(Continued)

Category B: Health Hazards	Definitions
Materials that have acutely endangered or killed workers	Has acutely endangered the life of a worker of either sex, whether normal or medically disabled, or has caused death from exposure via the respiratory tract (excluding asphyxiation), skin or mouth except that substances or mixtures shall not be placed in this category if available data permit their classification as "highly toxic" or "toxic".
Materials that cause other acute adverse health effects	Causes the immediate or delayed onset of other acute or subacute adverse health effects in humans of either sex, normal or medically disabled, or experimental or domestic animals, if animal models of these human health effects are available.
(2) Chronic Health Hazards	
Sensitizers	Causes humans of either sex, normal or medically disabled, or other mammals to develop either a hypersensitive allergic reaction involving normal tissue upon reapplication of the substance or mixture, or a photodynamic reaction. The hypersensitive reaction may be of the anaphylactic, immediate, delayed or fixed type, and may be of acute, subacute or chronic duration.
Carcinogen	Meets the definition of a Potential Occupational Carcinogen as specified in 29 CFR 1990.103 and qualified in 29 CFR 1990.143-144 (45 Fed. Reg. 5282, et seq., January 22, 1980) or is identified in a previous Occupational Safety and Health Administration regulation as a carcinogen (29 CFR Part 1910, Subpart Z).
Reproductive Toxins	Causes fetal wastage or undergrowth, malformation, growth retardation, or functional disorders in the products of mammalian conception, or prematurity or diminished fertility in mammals. For the purposes of regulation, it is immaterial whether a specific locus of action has been identified, assignment to this category being based upon the enumerated end-results.
Materials that cause other acute adverse health effects	Causes the immediate or delayed onset of other chronic adverse health effects in humans of either sex, normal or medically disabled, or experimental or domestic animals, if animal models of these human health effects are available.

Source: OSHA's Proposed Hazard Identification and Labeling Rule, 29 CFR 1910, 46 FR 4412, January 16, 1981.

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APPENDIX A

AIR CONTAMINANTS

EXHIBIT A1

CEILING VALUES & TIME WEIGHTED AVERAGES[a/]

Substance	p.p.m.*	mg./M^3 †
Acetaldehyde	200	360
Acetic acid	10	25
Acetic anhydride	5	20
Acetone	1,000	2,400
Acetonitrile	40	70
Acetylene dichloride, see 1, 2-Dichloroethylene		
Acetylene tetrabromide	1	14
Acrolein	0.1	0.25
Acrylamide—Skin		0.3
Aldrin—Skin		0.25
Allyl alcohol—Skin	2	5
Allyl chloride	1	3
C Allylglycidyl ether (AGE)	10	45
Allylpropyl disulfide	2	12
2-Aminoethanol, see Ethanolamine		
2-Aminopyridine	0.5	2
Ammonia	50	35
Ammonium sulfamate (Ammate)		15
n-Amyl acetate	100	525
sec-Amyl acetate	125	650
Aniline—Skin	5	19
Anisidine (o, p-isomers)—Skin		0.5
Antimony and compounds (as Sb)		0.5
ANTU (alpha naphthyl thiourea)		0.3
(Organic) Arsenic compounds (as As)		0.5
Arsine	0.05	0.2
Azinphos-methyl—Skin		0.2
Barium (soluble compounds)		0.5
p-Benzoquinone, see Quinone		
Benzoyl peroxide		5
Benzyl chloride	1	5
Biphenyl, see Diphenyl		
Boron oxide		15
C Boron trifluoride	1	3
Bromine	0.1	0.7
Bromoform—Skin	0.5	5
Butadiene (1, 3-butadiene)	1,000	2,200
Butanethiol, see Butyl mercaptan		
2-Butanone	200	590
2-Butoxy ethanol (Butyl Cellosolve)—Skin	50	240
Butyl acetate (n-butyl acetate)	150	710
sec-Butyl acetate	200	950
tert-Butyl acetate	200	950
Butyl alcohol	100	300
sec-Butyl alcohol	150	450
tert-Butyl alcohol	100	300
C Butylamine—Skin	5	15
C tert-Butyl chromate (as CrO_3)—Skin		0.1
n-Butyl glycidyl ether (BGE)	50	270
Butyl mercaptan	10	35
p-tert-Butyltoluene	10	60
Calcium arsenate		1
Calcium oxide		5
Camphor		2
Carbaryl (Sevin®)		5
Carbon black		3.5
Carbon dioxide	5,000	9,000
Carbon monoxide	50	55
Chlordane—Skin		0.5
Chlorinated camphene—Skin		0.5
Chlorinated diphenyl oxide		0.5
C Chlorine	1	3
Chlorine dioxide	0.1	0.3
C Chlorine trifluoride	0.1	0.4
C Chloroacetaldehyde	1	3
α-Chloroacetophenone (phenacylchloride)	0.05	0.3
Chlorobenzene (monochlorobenzene)	75	350

Substance	p.p.m.*	mg./M^3 †
o-Chlorobenzylidene malononitrile (OCBM)	0.05	0.4
Chlorobromomethane	200	1,050
2-Chloro-1,3-butadiene, see Chloroprene		
Chlorodiphenyl (42 percent Chlorine)—Skin		1
Chlorodiphenyl (54 percent Chlorine)—Skin		0.5
1-Chloro,2,3-epoxypropane, see Epichlorhydrin		
2-Chloroethanol, see Ethylene chlorohydrin		
Chloroethylene, see Vinyl chloride		
C Chloroform (trichloromethane)	50	240
1-Chloro-1-nitropropane	20	100
Chloropicrin	0.1	0.7
Chloroprene (2-chloro-1,3-butadiene)—Skin	25	90
Chromium, sol. chromic, chromous salts as Cr		0.5
Metal and insol. salts		1
Coal tar pitch volatiles (benzene soluble fraction) anthracene, BaP, phenanthrene, acridine, chrysene, pyrene		0.2
Cobalt, metal fume and dust		0.1
Copper fume		0.1
Dusts and Mists		1
Cotton dust (raw)		1
Crag® herbicide		15
Cresol (all isomers)—Skin	5	22
Crotonaldehyde	2	6
Cumene—Skin	50	245
Cyanide (as CN)—Skin		5
Cyclohexane	300	1,050
Cyclohexanol	50	200
Cyclohexanone	50	200
Cyclohexene	300	1,015
Cyclopentadiene	75	200
2, 4-D		10
DDT—Skin		1
DDVP—Skin		1
Decaborane—Skin	0.05	0.3
Demeton®—Skin		0.1
Diacetone alcohol (4-hydroxy-4-methyl-2-pentanone)	50	240
1,2-diaminoethane, see Ethylenediamine		
Diazomethane	0.2	0.4
Diborane	0.1	0.1
Dibutyl phosphate	1	5
Dibutylphthalate		5
C o-Dichlorobenzene	50	300
p-Dichlorobenzene	75	450
Dichlorodifluoromethane	1,000	4,950
1,3-Dichloro-5,5-dimethyl hydantoin		0.2
1,1-Dichloroethane	100	400
1,2-Dichloroethylene	200	790
C Dichloroethyl ether—Skin	15	90
Dichloromethane, see Methylenechloride		
Dichloromonofluoromethane	1,000	4,200
C 1,1-Dichloro-1-nitroethane	10	60
1,2-Dichloropropane, see Propylenedichloride		
Dichlorotetrafluoroethane	1,000	7,000
Dieldrin—Skin		0.25
Diethylamine	25	75
Diethylamino ethanol—Skin	10	[illegible]
Diethylether, see Ethyl ether		
Difluorodibromomethane	100	860
C Diglycidyl ether (DGE)	0.5	2.8
Dihydroxybenzene, see Hydroquinone		
Diisobutyl ketone	50	290
Diisopropylamine—Skin	5	20

Substance	p.p.m.*	mg./M^3 †
Dimethoxymethane, see Methylal		
Dimethyl acetamide—Skin	10	35
Dimethylamine	10	18
Dimethylaminobenzene, see Xylidene		
Dimethylaniline (N-dimethylaniline)—Skin	5	25
Dimethylbenzene, see Xylene		
Dimethyl 1,2-dibromo-2,2-dichloroethyl phosphate, (Dibrom)		3
Dimethylformamide—Skin	10	30
2,6-Dimethylheptanone, see Diisobutyl ketone		
1,1-Dimethylhydrazine—Skin	0.5	1
Dimethylphthalate		5
Dimethylsulfate—Skin	1	5
Dinitrobenzene (all isomers)—Skin		1
Dinitro-o-cresol—Skin		0.2
Dinitrotoluene—Skin		1.5
Dioxane (Diethylene dioxide)—Skin	100	360
Diphenyl	0.2	1
Diphenylmethane diisocyanate (see Methylene bisphenyl isocyanate (MDI))		
Dipropylene glycol methyl ether—Skin	100	600
Di-sec, octyl phthalate (Di-2-ethylhexylphthalate)		5
Endrin—Skin		0.1
Epichlorhydrin—Skin	5	19
EPN—Skin		0.5
1,2-Epoxypropane, see Propyleneoxide		
2,3-Epoxy-1-propanol, see Glycidol		
Ethanethiol, see Ethylmercaptan		
Ethanolamine	3	6
2-Ethoxyethanol—Skin	200	740
2-Ethoxyethylacetate (Cellosolve acetate)—Skin	100	540
Ethyl acetate	400	1,400
Ethyl acrylate—Skin	25	100
Ethyl alcohol (ethanol)	1,000	1,900
Ethylamine	10	18
Ethyl sec-amyl ketone (5-methyl-3-heptanone)	25	130
Ethyl benzene	100	435
Ethyl bromide	200	890
Ethyl butyl ketone (3-Heptanone)	50	230
Ethyl chloride	1,000	2,600
Ethyl ether	400	1,200
Ethyl formate	100	300
C Ethyl mercaptan	10	25
Ethyl silicate	100	850
Ethylene chlorohydrin—Skin	5	16
Ethylenediamine	10	25
C Ethylene glycol dinitrate and/or Nitroglycerin—Skin	0.2	1
Ethylene glycol monomethyl ether acetate, see Methyl cellosolve acetate		
Ethylene imine—Skin	0.5	1
Ethylene oxide	50	90
Ethylidine chloride, see 1,1-Dichloroethane		
N-Ethylmorpholine—Skin	20	94
Ferbam		15
Ferrovanadium dust		1
Fluoride (as F)		2.5
Fluorine	0.1	0.2
Fluorotrichloromethane	1,000	5,600
Formic acid	5	9
Furfural—Skin	5	20
Furfuryl alcohol	50	200

[a/] Exposure to any material preceded by a "C" shall at no time exceed the value given in the table. Exposure to all other materials in the table (those without a "C") shall at no time exceed the 8 hour time weighted average given. (29 CFR 1910.1000)

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APPENDIX A (Continued)

AIR CONTAMINANTS

EXHIBIT A1

CEILING VALUES & TIME WEIGHTED AVERAGES

Substance	p.p.m.[a]	mg./M³ [b]
Glycidol (2,3-Epoxy-1-propanol)	50	150
Glycol monoethyl ether, see 2-Ethoxyethanol		
Guthion ®, see Azinphosmethyl		
Hafnium		0.5
Heptachlor—Skin		0.5
Heptane (n-heptane)	500	2,000
Hexachloroethane—Skin	1	10
Hexachloronaphthalene—Skin		0.2
Hexane (n-hexane)	500	1,800
2-Hexanone	100	410
Hexone (Methyl isobutyl ketone)	100	410
sec-Hexyl acetate	50	300
Hydrazine—Skin	1	1.3
Hydrogen bromide	3	10
C Hydrogen chloride	5	7
Hydrogen cyanide—Skin	10	11
Hydrogen peroxide (90%)	1	1.4
Hydrogen selenide	0.05	0.2
Hydroquinone		2
C Iodine	0.1	1
Iron oxide fume		10
Isoamyl acetate	100	525
Isoamyl alcohol	100	360
Isobutyl acetate	150	700
Isobutyl alcohol	100	300
Isophorone	25	140
Isopropyl acetate	250	950
Isopropyl alcohol	400	980
Isopropylamine	5	12
Isopropylether	500	2,100
Isopropyl glycidyl ether (IGE)	50	240
Ketene	0.5	0.9
Lindane—Skin		0.5
Lithium hydride		0.025
L.P.G. (liquified petroleum gas)	1,000	1,800
Magnesium oxide fume		15
Malathion—Skin		15
Maleic anhydride	0.25	1
C Manganese		5
Mesityl oxide	25	100
Methanethiol, see Methyl mercaptan		
Methoxychlor		15
2-Methoxyethanol, see Methyl cellosolve		
Methyl acetate	200	610
Methyl acetylene (propyne)	1,000	1,650
Methyl acetylene-propadiene mixture (MAPP)	1,000	1,800
Methyl acrylate—Skin	10	35
Methylal (dimethoxymethane)	1,000	3,100
Methyl alcohol (methanol)	200	260
Methylamine	10	12
Methyl amyl alcohol, see Methyl isobutyl carbinol		
Methyl (n-amyl) ketone (2-Heptanone)	100	465
C Methyl bromide—Skin	20	80
Methyl butyl ketone, see 2-Hexanone		
Methyl cellosolve—Skin	25	80
Methyl cellosolve acetate—Skin	25	120
Methyl chloroform	350	1,900
Methylcyclohexane	500	2,000
Methylcyclohexanol	100	470
o-Methylcyclohexanone—Skin	100	460
Methyl ethyl ketone (MEK), see 2-Butanone		
Methyl formate	100	250
Methyl iodide—Skin	5	28
Methyl isobutyl carbinol—Skin	25	100
Methyl isobutyl ketone, see Hexone		
Methyl isocyanate—Skin	0.02	0.05
C Methyl mercaptan	10	20
Methyl methacrylate	100	410
Methyl propyl ketone, see 2-Pentanone		
C α Methyl styrene	100	480
C Methylene bisphenyl isocyanate (MDI)	0.02	0.2
Molybdenum:		
Soluble compounds		5
Insoluble compounds		15
Monomethyl aniline—Skin	2	9
C Monomethyl hydrazine—Skin	0.2	0.35
Morpholine—Skin	20	70
Naphtha (coaltar)	100	400
Naphthalene	10	50
Nickel carbonyl	0.001	0.007
Nickel, metal and soluble cmpds, as Ni		1
Nicotine—Skin		0.5
Nitric acid	2	5
Nitric oxide	25	30
p-Nitroaniline—Skin	1	6
Nitrobenzene—Skin	1	5
p-Nitrochlorobenzene—Skin		1
Nitroethane	100	310
C Nitrogen dioxide	5	9
Nitrogen trifluoride	10	29
C Nitroglycerin—Skin	0.2	2
Nitromethane	100	250
1-Nitropropane	25	90
2-Nitropropane	25	90
Nitrotoluene—Skin	5	30
Nitrotrichloromethane, see Chloropicrin		
Octachloronaphthalene—Skin		0.1
Octane	500	2,350
Oil mist, mineral		5
Osmium tetroxide		0.002
Oxalic acid		1
Oxygen difluoride	0.05	0.1
Ozone	0.1	0.2
Paraquat—Skin		0.5
Parathion—Skin		0.1
Pentaborane	0.005	0.01
Pentachloronaphthalene—Skin		0.5
Pentachlorophenol—Skin		0.5
Pentane	1,000	2,950
2-Pentanone	200	700
Perchloromethyl mercaptan	0.1	0.8
Perchloryl fluoride	3	13.5
Petroleum distillates (naphtha)	500	2,000
Phenol—Skin	5	19
p-Phenylene diamine—Skin		0.1
Phenyl ether (vapor)	1	7
Phenyl ether-biphenyl mixture (vapor)	1	7
Phenylethylene, see Styrene		
Phenyl glycidyl ether (PGE)	10	60
Phenylhydrazine—Skin	5	22
Phosdrin (Mevinphos ®)—Skin		0.1
Phosgene (carbonyl chloride)	0.1	0.4
Phosphine	0.3	0.4
Phosphoric acid		1
Phosphorus (yellow)		0.1
Phosphorus pentachloride		1
Phosphorus pentasulfide		1
Phosphorus trichloride	0.5	3
Phthalic anhydride	2	12
Picric acid—Skin		0.1
Pival ® (2-Pivalyl-1,3-indandione)		0.1
Platinum (Soluble Salts) as Pt		0.002
Propane	1,000	1,800
n-Propyl acetate	200	840
Propyl alcohol	200	500
n-Propyl nitrate	25	110
Propylene dichloride	75	350
Propylene imine—Skin	2	5
Propylene oxide	100	240
Propyne, see Methylacetylene		
Pyrethrum		5
Pyridine	5	15
Quinone	0.1	0.4
Rhodium, Metal fume and dusts, as Rh		0.1
Soluble salts		0.001
Ronnel		15
Rotenone (commercial)		5
Selenium compounds (as Se)		0.2
Selenium hexafluoride	0.05	0.4
Silver, metal and soluble compounds		0.01
Sodium fluoroacetate (1080)—Skin		0.05
Sodium hydroxide		2
Stibine	0.1	0.5
Stoddard solvent	500	2,950
Strychnine		0.15
Sulfur dioxide	5	13
Sulfur hexafluoride	1,000	6,000
Sulfuric acid		1
Sulfur monochloride	1	6
Sulfur pentafluoride	0.025	0.25
Sulfuryl fluoride	5	20
Systox, see Demeton ®		
2,4,5T		10
Tantalum		5
TEDP—Skin		0.2
Tellurium		0.1
Tellurium hexafluoride	0.02	0.2
TEPP—Skin		0.05
C Terphenyls	1	9
1,1,1,2-Tetrachloro-2,2-difluoroethane	500	4,170
1,1,2,2-Tetrachloro-1,2-difluoroethane	500	4,170
1,1,2,2-Tetrachloroethane—Skin	5	35
Tetrachloromethane, see Carbon tetrachloride		
Tetrachloronaphthalene—Skin		2
Tetraethyl lead (as Pb)—Skin		0.075
Tetrahydrofuran	200	590
Tetramethyl lead (as Pb)—Skin		0.075
Tetramethyl succinonitrile—Skin	0.5	3
Tetranitromethane	1	8
Tetryl (2,4,6-trinitrophenylmethylnitramine)—Skin		1.5
Thallium (soluble compounds)—Skin as Tl		0.1
Thiram		5
Tin (inorganic cmpds, except oxides)		2
Tin (organic cmpds)		0.1
C Toluene-2,4-diisocyanate	0.02	0.14
o-Toluidine—Skin	5	22
Toxaphene, see Chlorinated camphene		
Tributyl phosphate		5
1,1,1-Trichloroethane see Methyl chloroform		
1,1,2-Trichloroethane—Skin	10	45
Titaniumdioxide		15
Trichloromethane, see Chloroform		
Trichloronaphthalene—Skin		5
1,2,3-Trichloropropane	50	300
1,1,2-Trichloro 1,2,2-trifluoroethane	1,000	7,600
Triethylamine	25	100
Trifluoromonobromomethane	1,000	6,100
2,4,6-Trinitrophenol, see Picric acid		
2,4,6-Trinitrophenylmethylnitramine, see Tetryl		
Trinitrotoluene—Skin		1.5
Triorthocresyl phosphate		0.1
Triphenyl phosphate		3
Turpentine	100	560
Uranium (soluble compounds)		0.05
Uranium (insoluble compounds)		0.25
C Vanadium:		
V_2O_5 dust		0.5
V_2O_5 fume		0.1
Vinyl benzene, see Styrene		
Vinylcyanide, see Acrylonitrile		
Vinyl toluene	100	480
Warfarin		0.1
Xylene (xylol)	100	435
Xylidine—Skin	5	25
Yttrium		1
Zinc chloride fume		1
Zinc oxide fume		5
Zirconium compounds (as Zr)		5

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APPENDIX A (Continued)

EXHIBIT A2

8-HOUR TIME WEIGHTED AVERAGES & CEILING CONCENTRATIONS

Material	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling concentration for an 8-hour shift.	
			Concentration	Maximum duration
Benzene (Z37.4-1969)¹	10 p.p.m.	25 p.p.m.	50 p.p.m.	10 minutes.
Beryllium and beryllium compounds (Z37.29-1970)	2 μg./M³	5 μg./M³	25 μg./M³	30 minutes.
Cadmium dust (Z37.5-1970)	0.2 mg./M³	0.6 mg./M³		
Cadmium fume (Z37.5-1970)	0.1 mg./M³	0.3 mg./M³		
Carbon disulfide (Z37.3-1968)	20 p.p.m.	30 p.p.m.	100 p.p.m.	30 minutes.
Carbon tetrachloride (Z37.17-1967)	10 p.p.m.	25 p.p.m.	200 p.p.m.	5 minutes in any 4 hours.
Chromic acid and chromates (Z37.7-1971)		1 mg./10M³		
Ethylene dibromide (Z37.31-1970)	20 p.p.m.	30 p.p.m.	50 p.p.m.	5 minutes.
Ethylene dichloride (Z37.21-1969)	50 p.p.m.	100 p.p.m.	200 p.p.m.	5 minutes in any 3 hours.
Fluoride as dust (Z37.28-1969)	2.5 mg./M³			
Formaldehyde (Z37.16-1967)	3 p.p.m.	5 p.p.m.	10 p.p.m.	30 minutes.
Hydrogen fluoride (Z37.28-1969)	3 p.p.m.			
Hydrogen sulfide (Z37.2-1966)		20 p.p.m.	50 p.p.m.	10 minutes once only if no other measurable exposure occurs.
Lead and its organic compounds (Z 37.11-1969)	0.2 mg/m³			
Mercury (Z37.8-1971)		1 mg./10M³		
Methyl Chloride (Z37.18-1969)	100 p.p.m.	200 p.p.m.	300 p.p.m.	5 minutes in any 3 hours.
Methylene Chloride (Z37.23-1969)	500 p.p.m.	1,000 p.p.m.	2,000 p.p.m.	5 minutes in any 2 hours.
Organo (alkyl) mercury (Z37.30-1969)	0.01 mg./M³	0.04 mg./M³		
Styrene (Z37.15-1969)	100 p.p.m.	200 p.p.m.	600 p.p.m.	5 minutes in any 3 hours.
Tetrachloroethylene (Z37.22-1967)	100 p.p.m.	200 p.p.m.	300 p.p.m.	5 minutes in any 3 hours.
Toluene (Z37.12-1967)	200 p.p.m.	300 p.p.m.	500 p.p.m.	10 minutes.
Trichloroethylene (Z37.19-1967)	100 p.p.m.	200 p.p.m.	300 p.p.m.	5 minutes in any 2 hours.

[1] Occupational exposures to benzene are subject to the requirements of Section 1910.1028 except as specifically exempted by Section 1910.1028(a)(2). Exposures exempted by Section 1910.1028(a)(2) are covered by this Section 1910.1000.

EXHIBIT A3

MINERAL DUSTS

Substance	Mppcf ᵃ	Mg/M³
Silica:		
Crystalline:		
Quartz (respirable)	$\frac{250^{b}}{\%SiO_2+5}$	$\frac{10mg/M^3\ ^{c}}{\%SiO_2+2}$
Quartz (total dust)		$\frac{30mg/M^3}{\%SiO_2+2}$
Cristobalite: Use ½ the value calculated from the count or mass formulae for quartz.		
Tridymite: Use ½ the value calculated from the formulae for quartz.		
Amorphous, including natural diatomaceous earth	20	$\frac{80mg/M^3}{\%SiO_2}$
Silicates (less than 1% crystalline silica):		
Mica	20	
Soapstone	20	
Talc (non-asbestos form)	20ᵈ	
Talc (fibrous). Use asbestos limit		
Tremolite (see talc, fibrous)		
Portland cement	50	
Graphite (natural)	15	
Coal dust (respirable fraction less than 5% SiO₂)		2.4mg/M³ or
For more than 5% SiO₂		$\frac{10mg/M^3}{\%SiO_2+2}$
Inert or Nuisance Dust:		
Respirable fraction	15	5mg/M³
Total dust	50	15mg/M³

NOTE: Conversion factors—
mppcf X 35.3 = million particles per cubic meter
= particles per c.c.

ᵃ Millions of particles per cubic foot of air, based on impinger samples counted by light-field techniques.

ᵇ The percentage of crystalline silica in the formula is the amount determined from air-borne samples, except in those instances in which other methods have been shown to be applicable.

ᶜ Both concentration and percent quartz for the application of this limit are to be determined from the fraction passing a size-selector with the following characteristics:

ᵈ Containing < 1% quartz; if > 1% quartz, use quartz limit.

DEPARTMENT OF TRANSPORTATION

Both the Department of Transportation's Materials Transportation Bureau (MTB) and the U.S. Coast Guard (USCG) promulgate regulations concerning the transport and handling of hazardous chemicals as authorized by several statutes. These statutes are reviewed in the following pages:

DOT/MTB

- Explosives and Other Dangerous Articles Act
- Hazardous Materials Transportation Act (HMTA)

USCG

- Dangerous Cargo Act (DCA)
- Bulk Flammable and Combustible Liquids Act (BFCLA)
- Port and Waterways Safety Act (PWSA)

Although the HMTA authorizes DOT/MTB to regulate "any safety aspect" of the transportation of hazardous materials "by any mode," DOT retains independent regulatory authority under several other laws including the Federal Aviation Act, Federal Railway Safety Act, Motor Carrier Act, Natural Gas Pipeline Safety Act, and the Hazardous Liquid Pipeline Safety Act. These laws are not reviewed here.

The statutory and regulatory reviews that follow have not been reviewed by the Department of Transportation or the U.S. Coast Guard and do not necessarily represent the official position of those agencies. Moreover, this material does not necessarily represent EPA's official understanding of DOT (MTB/USCG) authority. The contractors ICF Incorporated and Lawrence W. Bierlein, P.C. are solely responsible for all interpretations and analyses.

DEPARTMENT OF TRANSPORTATION--STATUTORY REVIEW

EXPLOSIVES AND OTHER DANGEROUS ARTICLES ACT[1]

This statute was repealed very recently. Although it is no longer on the books and no longer serves to support specific regulatory action, its place in history provides much guidance in interpreting activities of hazardous materials transportation regulators to date. This is the statute under which the first hazardous materials transportation regulations (49 CFR 100-189) were issued by the Interstate Commerce Commission. Although more recent statutes now support those regulations, those regulations remain much as they were under the Explosives and Other Dangerous Articles (EODA) Act. In addition, references in other statutes and regulations to "explosives and other dangerous articles" may be traced to this statute.

Only six materials are mentioned in the definition section (Section 831) of the statute. Four of them are to delineate between similar-sounding items: detonating fuzes, fuzes, fuses, and fusees.

The two other definitions were added in 1960 in an effort to clarify authority over two types of hazards that the statute previously covered inaccurately as poisons: "'Radioactive materials' means any materials or combination of materials that spontaneously emit ionizing radiation;" and, "'Etiologic agents' means the causative agent of such diseases as may from time to time be listed in the regulations governing etiologic agents prescribed by the Interstate Commerce Commission under 18 USC 834."

Specific acts with regard to explosives were deemed criminal in Section 832. The materials were "dangerous explosives, such as and including, dynamite, blasting caps, detonating fuzes, black powder, gunpowder, or other like explosive." Joined with these explosives were radioactive materials and etiologic agents. Paragraph (b) of this statutory section listed certain other explosives (liquid nitroglycerin, fulminate in bulk in dry condition) "or other similarly dangerous explosives," or radioactive materials or etiologic agents. The regulating agency was given the power "from time to time to determine and prescribe what explosives are 'other similarly dangerous explosives.'" Other than by the examples of nitroglycerin and fulminate, no guidance was given to the agency to make this determination.

Section 834 provided authority to "formulate regulations for the safe transportation within the United States of explosives and other dangerous articles, including radioactive materials, etiologic agents, flammable liquids, flammable solids, oxidizing materials, corrosive liquids, compressed gases, and poisonous substances." These terms, generally called classifications, were not defined by the definition section of the statute (Section 831), but served to provide examples to the agency of the types of hazard to be regulated in transportation.

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[1] 18 USC § 831-835.

The regulations were to be "in accord with the best-known practicable means for securing safety in transit." Generally speaking, therefore, the authority was limited to governing materials that posed a threat of acute injury or infection while being transported. Concern for property was addressed only indirectly, in Section 832, where the regulating agency was given the power to allow small quantity shipments on passenger vehicles that were determined "to involve no appreciable danger to persons or property." Other references to property are in describing non-passenger carriers as carriers of property, as that class of commercial entity is regulated by the Interstate Commerce Commission.

HAZARDOUS MATERIALS TRANSPORTATION ACT[2]

This statute, frequently referenced as the HMTA, supplanted the Explosives and Other Dangerous Articles Act as the legislative basis upon which the Department of Transportation (DOT) issues and administers the Hazardous Materials Transportation Regulations, 49 CFR 100-189.

This regulatory authority under the Explosives and Other Dangerous Articles Act had been limited to carriers engaged in interstate or foreign commerce and their shipper customers. The regulating agency's authority and jurisdiction were broadened to permit DOT to govern transportation that is both interstate commerce or that "affects" interstate commerce. This generally is recognized as the broadest grant of authority Congress can make under the Commerce Clause of the Constitution.

The HMTA contains a general definition to guide the Secretary of Transportation in designating materials as hazardous. "Hazardous material" is defined in Section 1802(2) as "a substance or material in a quantity and form which may pose an unreasonable risk to health and safety or property when transported in commerce." The transportation intended includes "any movement of property by any mode, and loading, unloading, or storage incidental" to the transportation. The term "property" in this context is not defined.

Section 1803 gives DOT broad "discretion" to designate materials for regulation. Upon a Secretarial "finding . . . that the transportation of a particular quantity and form of material in commerce may pose an unreasonable risk to health and safety or property, he shall designate such quantity and form of material or group or class of such materials as a hazardous material." While there is reference to "findings" and to "designation," the statute is silent on the mechanism for these functions, but it has been assumed that the rule making power granted to DOT under Section 1804 of the HMTA is at least one appropriate mechanism that may be used. The materials designated may include, but are not limited to, "explosives, radioactive materials, etiologic agents, flammable liquids or solids, combustible liquids or solids, poisons, oxidizing or corrosive materials, and compressed gases." These terms, however, are not statutorily defined.

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[2] 49 USC § 1801 et seq.

The section-by-section analysis of this statute in Senate Commerce Committee Report No. 93-1192, 93d Cong., 2d Sess., September 30, 1974, says of Section 1803: "This section provides that the Secretary is to designate a material or a quantity of material as a hazardous material after finding that the transportation of that material or a quantity or form of material in commerce may pose an unreasonable risk to health and safety or property. The Secretary is not limited in the kinds of materials which are within this purview; the section names certain kinds of possible hazardous materials by way of illustration rather than limitation." The series of "possible hazardous materials" given in the list of examples clearly is drawn from the similar series in Section 834 of the earlier Explosives and Other Dangerous Articles Act, discussed above.

The purpose of the statute is to give DOT the authority "to protect the Nation adequately against the risks to life and property which are inherent in the transportation of hazardous materials in commerce." (Section 1801.) Regulations authorized in Section 1805 "may govern any safety aspect of the transportation of hazardous materials which the Secretary deems necessary or appropriate, including, but not limited to, the packing, repacking, handling, labeling, marking, placarding, and routing (other than with respect to pipelines) of hazardous materials, and the manufacture, fabrication, marking, maintenance, reconditioning, repairing, or testing of a package or container which is represented, marked, certified, or sold by such person (sic) for use in the transportation of certain hazardous materials."

U.S. COAST GUARD--STATUTORY REVIEW

DANGEROUS CARGO ACT[3]

The Explosives and Other Dangerous Articles Act provided that regulations issued thereunder would be binding upon carriers engaged in interstate or foreign commerce by land, and the shippers who used their services, as well as upon shippers of hazardous materials via any carrier engaged in interstate or foreign commerce by water. The regulations, therefore, did not apply by their own terms to water carriers.

This coverage was provided by the Dangerous Cargo Act (DCA). Like the EODA Act, the DCA provides specific statutory prohibitions with regard to specifically identified materials. For example, under Section 170(3), no one may ship or carry "fulminates or other detonating compounds in bulk in dry condition, or explosive compositions that ignite spontaneously or undergo marked decomposition when subjected for forty-eight consecutive hours to a temperature of one hundred and sixty-seven degrees Fahrenheit, or compositions containing an ammonium salt and a chlorate, or other like explosive." It is unlawful under Section 170(4) to carry on any passenger vessel "any high explosives such as, and including, liquid nitroglycerin, dynamite, trinitrotoluene, picrates, detonating fuzes, fireworks that can be exploded en masse, or other explosives susceptible to detonation by a blasting cap or detonating fuze."

Regulations issued by the Coast Guard must be followed in transporting or using aboard vessel "any other explosives or other dangerous articles or substances, including flammable or combustible liquids, flammable solids, oxidizing materials, corrosive or combustible liquids, compressed gases, poisonous articles or substances, hazardous articles, and ships' stores and supplies of a dangerous nature." (Section 170(6).)

Section 170(7) compels the Coast Guard, however, to accept and adopt the "definitions, descriptions, descriptive names (and) classifications" that were adopted under the Explosives and Other Dangerous Articles Act for applicability to shippers by water.

BULK FLAMMABLE AND COMBUSTIBLE LIQUIDS ACT (BFCLA)[4]

This statute vests the Coast Guard with broad authority over tank vessels, which carry hazardous materials in bulk (not packaged or containerized). By regulation, non-bulk quantities are governed under the HMTA, and bulk quantities are under Section 391a, although there is no limitation in the HMTA that compels this division. Section 391a is based upon a Congressional statement of policy that declares "the carriage by vessels of certain cargoes in bulk or in residue creates substantial hazards to life, property, the navigable waters of the United States (including the quality thereof) and the resources contained therein and to the adjoining land, including but not limited to fish, shellfish, and wildlife, marine and coastal ecosystems, and recreational and scenic values (Section 391a(A))."

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[3] 46 USC § 170.

[4] 46 USC § 391a.

While granting substantial regulatory power to the Coast Guard, the discretion to designate materials is limited by the Statute. The BFCLA, in paragraph (2)(C), defines "hazardous materials" as "any liquid material or substance which is -- (i) flammable or combustible; or (ii) designated a hazardous substance under Section 311(b) of the Federal Water Pollution Control Act, as amended (33 USC § 1321(b)); or (iii) designated a hazardous material under Section 104 of the Hazardous Materials Transportation Act (49 USC § 1803)."

The "marine environment" is defined in paragraph (2)(D) as including all navigable waters, all waters and fishery resources over which jurisdiction is asserted by the U.S., the seabed and subsoil of the Outer Continental Shelf as well as the waters and resources adjacent thereto, and the recreational, economic, and scenic values of such waters and resources. Congress found existing standards must be more stringent and comprehensive for the mitigation of the hazards to life, property, and the marine environment.

An interesting feature of the BFCLA is its treatment of the economic costs associated with protective standards. Regulations are to be based on Best Available Technology (BAT) unless the result is undue economic impacts which are not outweighed by the benefits of the standards. The approach used by the EPA to establish National Emission Standards for Hazardous Air Pollutants bears some similarities to this mandate: EPA's policy is to establish a level of protection based on Best Available Technology supplemented by a consideration of the reasonableness of the residual risk, if any.[5]

PORTS AND WATERWAYS SAFETY ACT[6]

This statute is both a safety and an environmental protection act. The Congressional declaration of policy in Section 1221 declares, among other things, "that nagivation and vessel safety and protection of the marine environment are matters of major national importance." Congress further notes that increased supervision of vessel and port operations is necessary "to reduce the possibility of vessel or cargo loss, or damage to life, property, or the marine environment," and "to insure that the handling of dangerous articles and substances on the structures in, on, or immediately adjacent to the navigable waters of the United States is conducted in accordance with established standards and requirements."

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[5] See complete discussion in Regulatory Review, Clean Air Act, Section 112.

[6] 33 USC § 1221 et seq.

The Coast Guard may issue broad vessel operating requirements under Section 1223. In carrying out these responsibilities, the Secretary of the Department within which the Coast Guard is located must "take into account all relevant factors concerning navigation and vessel safety and protection of the marine environment, including but not limited to (1) the scope and degree of the risk or hazard involved; (2) . . . the presence of any unusual cargoes; . . . (6) environmental factors; and (7) economic impact and effects. . . ."

With regard to waterfront safety, the Secretary may take such action as is necessary "to protect the navigable waters and the resources therein from harm resulting from vessel or structure damage, destruction, or loss. Such action may include, but need not be limited to (A) establishing procedures, measures, and standards for the handling, loading, unloading, storage, stowage, and movement on the structure (including the emergency removal, control, and disposition) of explosives or other dangerous articles and substances, including oil or hazardous materials as those terms are defined in Section 4417a of the Revised Statutes, as amended (46 USC § 391a) . . . ." Oil is defined in Section 391a of "oil of any kind or in any form, including, but not limited to, petroleum, fuel oil, sludge, oil refuse, and oil mixed with wastes other than dredged spoil." Hazardous mateial is defined to include all hazardous substances designated under Section 311 of the Clean Water Act and all hazardous materials designated under the Hazardous Materials Transportation Act.

DEPARTMENT OF TRANSPORTATION -- REGULATORY REVIEW[7]

The following reviews discuss regulations promulgated under the
reviewed previously. The first regulatory review covers hazardous m
regulations promulgated under HMTA, the second review covers those
administered by the Coast Guard. Only regulations proposed or promu
through January 1, 1981 are included.

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[7] The regulatory reviews of DOT and USCG regulations were prepare
Lawrence W. Bierlein, P.C., subcontractor to ICF Incorporated.

HAZARDOUS MATERIALS TRANSPORTATION ACT--REGULATORY REVIEW

INTRODUCTION

The majority of this regulatory review will focus on the hazardous materials transportation regulations administered now by the Department of Transportation (DOT). The need for this focus is the multitude of other regulatory schemes that adopt or cross reference DOT hazard designations. Throughout transportation, but also in non-transportation regulatory programs, the influence of the DOT regulations is felt. This impact is not necessarily considered by DOT or reviewed by other program managers when basic DOT changes are made. Therefore, it is essential to have a thorough knowledge of the core of these regulations, in order to assess the merit of their utility in other contexts.

The federal Hazardous Materials Regulations are published by DOT in Parts 100-189 of Title 49 CFR. The regulations are issued under the authority of the Hazardous Materials Transportation Act (HMTA), 49 USC § 1801, 1804. They may be applied to all carriers and shippers of hazardous materials, and all makers of packaging sold for hazardous materials, moving in commerce "affecting" interstate or foreign commerce.

Section 1803 of the HMTA, describing DOT's authority to designate hazardous materials, authorizes controls over any materials including "but not limited to" explosives, radioactive materials, etiologic agents, flammable liquids or solids, combustible liquids or solids, poisons, oxidizing or corrosive materials, and compressed gases. (See the Statutory Review for further details). The HMTA regulations to date have only been expanded significantly beyond those enumerated hazards to accommodate EPA-designed hazardous substances and hazardous wastes in the ORM-E class, described more fully below.

Under Section 1803, in order to designate a material as hazardous, the Secretary of Transportation must find it is in a quantity and form that may pose an unreasonable risk to health and safety or property in transportation. There is no separate procedural mechanism to identify new materials to be brought under transportation regulatory controls. To date, to the extent designation has occurred under the HMTA, it has taken place in the informal and loosely structured dialogue of agency rulemaking. The regulations currently appearing in 49 CFR were issued as HMTA regulations with an effective date of January 3, 1977, but the rules did not come into being at that time. They had been in place for many decades, administered first by the Interstate Commerce Commission and then by DOT under authority contained in the Explosives and Other Dangerous Articles Act, 18 USC § 831-835 (since repealed).

Neither the facts necessary for designation of new hazardous materials under the HMTA nor the quantitative criteria upon which a designation decision would be based are specified by DOT, and perhaps are not even known. developed no systematic method for risk assessment or evaluation. T consistent consideration of the quantity or form of materials in mak assessment. There is no known "level of safety" in the regulations. no assurance of consistency in controls, from commodity to commodity to hazard, mode to mode, quantity to quantity, or day to day.

The system, such as it is, has evolved piecemeal over the past t quarters of a century. It is a development in which all judgment has subjective and all requirements negotiated. To fail to recognize thi seek more substance and rationality in the DOT regulations than exist there are many inconsistencies and illogical elements to the DOT Haza Materials Regulations, as well as many clear errors. This is particu true when reviewing parallel regulations implemented and administere Coast Guard in 49 CFR.

The system of regulation administered by DOT requires the classif of a material to provide a "handle" for the regulatory mechanism. I words, to be subject to substantive requirements under the DOT regula material must first be categorized into one of the existing class de of hazardous materials, even if it is not specifically listed in the regulations. DOT defines the classes and it is the shipper's burden opportunity to describe his materials according to the most appropria definition.

The issue of proper classification of materials having multiple h addressed in 49 CFR 173.2, where a "pecking order" of classification offered. For certain materials such as explosives and blasting agent however, the classfication function is considered so important and th classification tests so dangerous that the function is not relegated shipper, but is reserved to specified agencies or laboratories. For materials listed by name in 49 CFR 172.101 with a "+" mark, the class is mandated by the table. For the most part, however, it is up to th to identify his materials, to determine the correct DOT classificati them, to select the proper shipping name from the list in 49 CFR 172. then to comply with all requirements applicable to that description. DOT may request data on how a given shipper reached his conclusions, no obligation to file this information with any agency as a matter of nor is there an obligation to have such data on file. The classifica decision, which bears so heavily on the requirements related to a giv material, is one of the most complex a shipper makes and is the one he is given the least guidance by DOT.

In the process of defining hazard classifications, no formal cons is given by the agency to the economic impact of their decision. Of like all agencies, there is compliance with the executive orders on impact that may be current, but the process is not formalized at DOT. presumed that any proposal that will have a significant economic impa any party will stimulate that party to raise the issue. In cases of impact, the agency is likely to be persuaded to ameliorate its proposal. In no clear sense, however, is there any agency program or obligation to choose the less expensive of two proposals that may work equally well.

DOT has the authority to expand and revise the classifications and has done so in recent years with the creation of the Blasting agent and Other Regulated Materials (ORM-A, B, C, D, and E) classes. While many ORM-A, B, C, and D materials had been subject to some controls in transportation, the rule changes creating the ORM classes made applicability of the federal regulations clearer.

Currently regulated DOT classifications and their 49 CFR definition sections are as follows:

Explosives, Class A, B and C (173.50, 173.53, 173.88, and 173.100)
Blasting agents (173.114a)
Flammable and Combustible liquids (173.115)
Flammable solids (173.150)
Oxidizers (173.151)
Organic peroxides (173.151a)
Corrosive materials (liquid and solid) (173.240)
Compressed gases (flammable and non-flammable) (173.300)
Poisons, Class A and B (173.326 and 173.343)
Irritating materials (173.381)
Etiologic agents (173.386)
Radioactive materials (173.389)
ORM-A, B, C, D and E (173.500)

In virtually every classification, there is a mechanism whereby hazardous materials that do not exactly "fit" the class may be relegated to that class nonetheless. In addition, for some classes there is a method to remove the material from the class despite the fact that it does fit technically. The legality of this awkward process has never been challenged. As the various classifications are described below, those paragraphs by which DOT adopts the fit of the classification will be highlighted. In general these are little used mechanisms with almost no procedural precedent, and they are unlikely to be used extensively in the future. The above classifications will each be described in turn.

EXPLOSIVES AND BLASTING AGENTS

An explosive (whether Class A, B, or C) is defined as "any chemical compound, mixture, or device, the primary or common purpose of which is to function by explosion, i.e., with substantially instantaneous release of gas and heat, unless such compound, mixture, or device is otherwise specifically classified" elsewhere in the DOT regulations.

The explosives classification is an oddity. It is the one DOT classi
cation (along with the related Blasting agent class) not left to the disc
tion of the shipper of the product. The shipper of an article that may b
explosive first must submit that material to the Bureau of Explosives, a
nical arm of the Association of American Railroads. This is a private, n
governmental laboratory that for over 75 years has performed this functic
After testing, the Bureau of Explosives will classify the material and,
is assigned to the explosives class, will prescribe the A, B or C designa
tion. Under 49 CFR 173.86, the classification of commercial explosives
reserved to the Bureau of Explosives. Explosives developed for the Ener
Research and Development Administration or the Army may be classified by
two agencies.) While there is no shipper discretion to classify explosi
the shipper does have the obligation to know that there are materials
described in 49 CFR 173.51 that are forbidden in transportation. These
materials are so unstable that they may not be transported by any mode a
time.

Class A explosives are defined by eight types and by such generic de
scriptions as "ammunition for cannon," "explosive projectiles," "grenade
and the like. The type definitions of Class A explosives relate to the
tivity of the material stated in terms of its sensitivity to testing wit
varying size blasting caps, or to dropping or exposure to heat.

Class B explosives are those that "deflagrate," or function by rapic
bustion rather than by detonation. These include explosive devices suc
special fireworks, flash powders, some pyrotechnic signal devices, and
or solid propellant explosives. Here again, materials in the Class B
explosives classification are assigned to that class by the Bureau of
Explosives. They fit within specific descriptions given in 49 CFR 173.
which purports to define this class. This in fact is not a definition
but, rather, an assignment of shipping names to articles catregorized b
Bureau of Explosives as Class B explosives.

Class C explosives are the least hazardous materials in the explosi
classification. These are defined in 49 CFR 173.100 as manufactured ar
that contain Class A or Class B explosives or both as components, but
restricted quantities. Class C explosives include fireworks and small
ammunition. 49 CFR 173.100, while nominally a definition section, like
sections defining Classes A and B is made up of descriptions of materi
signed to these classes by the Bureau of Explosives rather than defini
per se.

Blasting agents has been recently designated by DOT as a new class
tion. In the initial amendment in DOT's Docket No. HM-143, two reason
given for the new class. The creation of a new class contributes to
safety in transportation because "some materials now shipped as nitro
nitrates (oxidizing materials) present a potential explosive hazard.
lishing a blasting agent class will bring the DOT regulations into clo
formity with Mining Enforcement and Safety Administration (MESA) and B

Alcohol, Tobacco and Firearms (BATF) regulations which now incorporate definitions of blasting agents." (43 FR 57898, December 11, 1978) With creation of the new class there were simultaneous creations of new shipping names, labels and placarding requirements for blasting agents.

A blasting agent is defined in 49 CFR 173.114a as, "a material designed for blasting which has been tested in accordance wih (prescribed test) and found to be so insensitive that there is very little probability of accidental initiation to explosion or of transition from deflagration to detonation. The definition includes tests that must be passed, including a blasting cap sensitivity test, a differential thermal analysis test, a thermal stability test, an electrostatic sensitivity test, an impact sensitivity test, and a fire test. After performance of the tests the manufacturer in addition must receive DOT approval for his assignment of the blasting agent classification, unless specific labaratories or agencies have written that there are no significant differences in hazard characteristics relative to a blasting agent already approved by DOT. The examination and tentative classification of new blasting agents must be done by the Bureau of Explosives, the Department of Energy or the Department of Defense.

While this is a new classification tied to the explosives group as opposed to the oxidizer goup, it is not an explosive A, B or C, but is an independent classifcation. The label on the blasting agents looks similar in color to an explosives label, but does not carry the "exploding bomb" UN symbol. DOT said in its final amendment that no symbol is displayed "due to the fact that blasting agents present a much lower level of hazard in terms of their detonation potential than Class A and B explosives for which an "exploding bomb" is displayed on the label."

As noted above, the Bureau of Explosives has the primary responsibility for assigning articles to the explosives class. The work of the Bureau of Explosives has evolved since the 19th century and has frequently been criticized for a lack of procedural consistency or quantification. Much of the classification decision is based upon the experience of the person running the test and his subjective reaction to the performance of materials in the test, relative to the performance of other materials in other tests. The Department of Transportation has long had a low priority project to revise the explosives classification to more quantitatively and consistently define materials in that class, but the conclusion of this rulemaking may be years away.

Another factor that must be noted about this class is that the classification is inextricably linked to the "primary or common purpose" of the material to function by explosion, as stated in the definition. Literally, this means that a material which may explode, but does not have the purpose of exploding, does not fit the DOT definition. While this factor has been raised in criticism of the definition, it has never been judicially resolved.

It should be noted that the "reactive" category in the EPA regulations under Section 3001 of the Resource Conservation and Recovery Act will include many explosives that are discarded, but that category does not overlap the explosives classification exactly.

FLAMMABLE AND COMBUSTIBLE LIQUIDS

49 CFR 173.115 declares that a DOT-regulated flammable liquid is one having a closed-cup flash point below 100°F. (37.8°C.), with certain speci exceptions. The exceptions basically are those which fall within the flammable liquid class by the closed-cup flash point tester, but by logic not fit it. These includes gases and materials having minor amounts of certain ingredients that give extremely low or high flash point readings i the closed tester, without regard to their true fire hazard.

A combustible liquid, defined in 49 CFR 173.115, is one posing less of flammability hazard, having a closed-cup flash point at or above 100°F. (3 C.) and below 200°F. (93.3°C.). The combustible liquid class also has cer exceptions based upon illogical results of test methods. For example, an aqueous solution containing 24% or less alcohol by volume is "considered t have" a flash point no less than 100°F., i.e., is a combustible liquid, if remainder of the solution does not meet the definition of another hazardou material. Such liquids are assigned to the combustible liquid class desp: the fact they otherwise meet the flammable liquid definition, because of misleading test results caused by the closed-up test method when applied t alcohol/water mixtures.

"Pyrophoric" liquids also are regulated by DOT and are described in 49 CFR 173.115, the class definition section, but they do not form a separate classification. For DOT purposes a pyrophoric liquid is any that ignites spontaneously in dry or moist air at or below 130°F. (54.5°C.).

The flammable and combustible liquid classes were revised by DOT over period of several years in the 1970's, in rulemaking Docket No. HM-102. primary purposes of the HM-102 redefinition of the flammable the combusti liquid classes were: (1) to raise the definition limit for flammable liq from 80°F. to 100°F., and (2) to change the basic methodology from the op the closed-cup tester. The first change was not justified on the basis o transportation safety but, rather, on administrative consistency with sim definitions under federal Occupational Safety and Health (OSHA) Regulatio (29 CFR 1910.106). A similar purpose was cited above, for creation of th Blasting agent class. The primary rationale for changing to the closed-c tester was a parallel drawn between a closed transportation vehicle and t closed-cup tester, in the trapping of fumes from a liquid that might not a reading of flammability in an open tester. The only other major federa definition of flammability at that time was administered by the Food and Administration but was prescribed by statute at 80°F (see statutory revie Federal Hazardous Substances Act).

The 100-200°F. combustible liquid flash point definition was taken from OSHA regulations as they reflected National Fire Protection Association (NFPA) standards. This is a classification of materials generally not subjected to substantive DOT regulations. No HMTA regulation applies to unit quantities smaller than 100 gallons (unless these materials are hazardous wastes or hazardous substances), and even in bulk land transportation the requirements are only of a communications nature -- shipping papers and vehicle placards. The primary concern with creation of the combustible liquid class was proper notification to fire personnel when a bulk unit of such materials was involved in an accident. Too many very burnable materials had been moving in tank trucks bearing a "Nonflammable" placard.

The suggestion in HM-102 rulemaking, that the class be defined by an upper flash point limit of 140° like the U.N. definition, was not adopted because there was no contention that liquids in this flash point range pose a safety hazard in transportation. As noted earlier, the shift from 80° to 100°F. also was unsupported on safety grounds, but was adopted because of the consistency thereby derived with the Occupational Safety and Health Regulations. EPA's recent adoption of an upper limit of 140°F. for its ignitable waste definition is not based upon transportation concerns, but upon disposal site considerations. Thus, a ten-gallon pail of an EPA ignitable waste with a flash point of 120°F. will be not be regulated as a flammable liquid under DOT, but will be consigned to the miscellaneous class of ORM-E, discussed more fully below.

49 CFR 173.115(g) of the DOT regulations is one of the unique provisions mentioned earlier, providing DOT with designation flexibility. It reads: "If experience or other data indicate that the hazard of a material is greater or less than indicated by the criteria specified (in the flammable liquid definition), the Department may revise its classification or make the material subject to the requirements" of the Hazardous Materials Regulations. A specific product of concern to DOT at the time of the HM-102 rulemaking was nitromethane, which does not meet the flash point definition of flammable liquid and yet had been involved in three major transportation explosions. When the flammable liquid class was redefined, this paragraph was inserted to provide a published mechanism by which a material not otherwise fitting the class could be forced into that class based upon experience or other data. Presumably a material could also be removed from the class, but to date this has not been done via this paragraph.

FLAMMABLE SOLIDS

The flammable solid class is described only generally in the DOT regulations. Under 49 CFR 173.150, the term includes "any solid material, other than one classed as an explosive, which, under conditions normally incident to transportaton is liable to cause fires through friction, retained heat from manufacturing or processing, or which can be ignited readily and when ignited burns so vigorously and persistently as to create a serious transportation hazard." This class includes spontaneously combustible solids and water-reactive materials.

As can be seen from this definition, there are several subjective and amorphous qualifications relevant to placement of a material in this class. Unlike the explosives classification, the assignment of a material to this class is entirely at the discrretion of the shipper of the material. Of course, however, if the material is classed by the Bureau of Explosives as an explosive, it definitely cannot also be in the flammable solid class. Under DOT interpretation, "conditions normally incident to transportation" do not include accident circumstances, but do include the vibration and abuse a material will receive in usual cargo transportation. In air transport these conditions also include variations in pressure, temperature, and humidity due to rapid changes in altitude. In land transportation they include all environmental conditions likely to be encountered, including temperatures up to 130°F.

There are three alternative elements to the definition. The material under normal conditions must pose the danger of causing fires through (1) friction, (2) retained heat, or (3) ready ignition accompanied by vigorous and persistent burning. None of these elements of the definition has been quantified.

The specific inclusion of water-reaction materials in the flammable solid class is caused by the DOT system of requiring a material to fall within an existing classification before it may be regulated. Water-reactive materials are defined in 49 CFR 171.8 as those which through interaction with water are likely to become spontaneously flammable or to give off flammable or toxic gases in dangerous quantities. Although a solid material that gives off a toxic gas when wet does not pose a flammability hazard, for administrative convenience it has been assigned to the flammable solid classification. An additional rationale for this assignment is that the most likely source of significant quantities of water in transportation is a fire hose, and warning fire personnel that the material becomes more hazardous when wet is the primary purpose of the regulation of water reactive materials. Through DOT's recently adopted four-digit hazard information system, emergency response personnel will be advised to the specific hazards of the material (flammability or toxicity) in a manual, and in the interim they will not have sprayed it with water.

The flammable solid classificaton, because of its subjective nature and its non-specific, unquantified terms, has been one of the most difficult to administer for DOT and shippers. It is presumed generally that a shipper in doubt will classify his material as a flammable solid if for no other reason than to minimize the civil liability that might attach in the event of an accident injuring third parties. In essence, this class would be assigned as part of the shipper's duty of due care to others, regardless of regulatory obligations.

Many people have sought to quantify this definition for their own purposes by having testing done by varous independent laboratories. It is known that the Bureau of Explosives will run tests and assign a classificaton if requested by a contracting shipper. For several years, DOT has had a low priority project underway to quantify this definition, but implementation of such changes is years away.

OXIDIZERS

DOT defines an oxidizer as a chlorate, permanganate, inorganic peroxide or nitrate that yields oxygen readily to stimulate the combustion of organic matter. Here again, while the definition is somewhat more specific than the flammable solid definition, the terms still are subject to varying interpretation. For example, it is unclear what level the oxygen yield must be to stimulate the combustion of organic matter to pose a danger in transportation.

With both the flammable solid and oxidizer classes, many materials recognized by DOT as being within these classifications are listed as such by name in the alphabetical table of materials in 49 CFR 172.101. When a material is not so listed, the shipper must determine on his own data and at his peril whether the definition and classification fit his material. In most cases, guidance on the applicability of the rules will not come until after the fact, i.e., after an accident or enforcement action leads to interpretation.

ORGANIC PEROXIDES

DOT defines organic peroxides in 49 CFR 173.151(a). The definition used to be linked directly with that of flammable solids and oxidizers but, in Docket No. HM-112, it was broken out as a specific classification to recognize the unique properties of these materials. An organic peroxide is "An organic compound containing the bivalent -0-0- structure which may be con- sidered a derivative of hydrogen peroxide where one or more of the hydrogen atoms have been replaced by organic radicals." Exceptions to this definition are materials that have been classed as explosives, materials forbidden in transportation because of their instability, materials meeting the definition of flammable liquids not specifically assigned to the organic peroxide class in 49 CFR 172.101.

In this classification, there is another provision giving DOT flexibility in their designation function. This one is in 49 CFR 173.151(a)(4), saying that any material meeting the definition of an organic peroxide must be so classed unless "according to data on file with the Materials Transportation Bureau, it has been determined that the material does not present a hazard in transportation." This paragraph, unlike the one discussed above with regard to flammable liquids, does not give the agency authority to put materials into the class that do not otherwise fit. It only provides a mechanism to take materials out of the class. The phrasing of this is also different from many of the other paragraphs on the same subject, since it only requires data to be on file at DOT and does not appear to require an agency response to finding to remove the material from the classification.

CORROSIVE MATERIALS

Corrosive liquids and solids are defined for DOT purposes in 49 CFR 173.240. A corrosive material is a liquid or solid that "causes a visible destruction or irreversible alterations in human skin tissue at the site of contact, or in the case of leakage from its packing a liquid that has a severe corrosion rate on steel." These general descriptions are quantified by a specific 4-hour rabbit skin test and a corrosion rate test on steel giving results in inches per year (0.250 IPY).

This classification has undergone fairly recent substantive revision in DOT's rulemaking Docket No. HM-57. This docket, concluded in the early 1970's, examined the quantification of the definition in light of specific tests to be run. HM-57 took the form of advanced notices of proposed rulemaking and several notices followed by an amendment and several corrective amendments, each making significant adjustments in the definition.

The rabbit skin test is described in Appendix A to part 173 of the DOT regulations. It is similar to, but not the same as, a now Consumer Product Safety Commission test methodology for skin irritants. (See regulatory review of Federal Hazardous Substances Act and analysis of generic hazard classifications in Volume I). The prominant factor in the DOT test is that the skin need not be abraded, and consequently many materials that might be found regulated under the other tests are not regulated by DOT. Tissue at the site of contact must be destroyed or changed irreversibly, and this has been clarified by DOT to mean actual necrosis of the tissue. Reddening or soreness or irritation that will heal does not fall within this definition.

Under the rabbit skin test an exposure period of four hours or less is prescribed. Longer periods were proposed in the early rulemaking, but it was determined by the agency that the likelihood of a transportation worker keeping spilled material on his hands without washing for a period in excess of four hours was so small as to not warrant regulation. The four-hour period is keyed to the typical transportation worker's day, where it is likely he will wash midway through the day prior to eating.

In the process of quantification of the corrosive classification in Docket No. HM-57, DOT considered and rejected a pH test as being a criterion not sufficiently broad to cover all materials that have a destructive effect on tissue. Notably, pH criteria exclude purely organic chemicals (such as amines), and also do not relate well on the basic (as opposed to acidic) side of the scale to materials corrosion.

For both DOT and EPA purposes, the corrosion rate on steel is determined by a recognized test of the National Association of Corrosion Engineers (NACE). DOT also proposed that materials corrosive to aluminum be regulated in land transportation but, for a variety of reasons including the particular concern with air transportation, the aluminum corrosive qualification was not adopted for all modes.

The corrosive materials classification, as many of those already discussed, includes a flexibility paragraph reading: "If human experience or other data indicate that the hazard of a material is greater or less than indicated by the results of the tests specified in (49 CFR 173.240(a)), the Department may revise its classification or make the material subject to the requirements" of the regulations. This paragraph, similar to that found under the flammable liquids classification, allows DOT on the basis of data other than prescribed test results to put a material in or take it out of the classification. Unlike the comparable oxidizer paragraph, the statement clearly requires some action on the part of DOT in response to the submission of information on human experience, or other data.

The corrosives definition revised in Docket No. HM-57 was significantly affected by international deliberations on a similar definition. It is known that additional work on the corrosives classification has been completed in the international forum and may result in changes to the DOT definition in the future.

Regulation of corrosives, particularly those that are not damaging to human tissue, is one of the few areas where DOT clearly controls materials because of a threat to property. Historically it is understood that the concern with property in transportation focuses on damage to transportation equipment and on other packaged freight moving with the regulated commodity. There is no historical record that the transportation regulatory concern with corrosive materials has ever extended to damage to the environment, i.e, damage to natural resources that could not be considered private property.

Even in its regulation of property-corrosive materials, DOT's primary concern has been the impact on transportation safety that might be caused through destruction of adjacent packaging containing other hazardous materials, or the destruction of a structural element of a transport vehicle leading to a transportation safety hazard. Mere damage to adjacent unregulated articles is a matter more appropriately left to commercial loss and damage claims procedures and has not received a great deal of consideration in the evolution of DOT's corrosive classification. Without question, development of the corrosive materials classification in its historical beginnings as well as in Docket No. HM-57 occurred without any consideration of impact on the environment caused by the spill of any hazardous materials.

COMPRESSED GASES (FLAMMABLE AND NONFLAMMABLE)

DOT defines compressed gas in 49 CFR 173.300. The term includes "any material or mixture having in the container an absolute pressure exceeding 40 p.s.i. at 70°F., or regardless of the pressure at 70°F., having an absolute pressure exceeding 104 p.s.i. at 130°F.; or any liquid flammable material having a vapor pressure exceeding 40 p.s.i. absolute at 100°F. as determined by ASTM Test T-323."

The concern addressed historically by the DOT regulations is safety in transportation. As a result, the gas definition is stated in terms of pressure that might be encountered under conditions normally incident to transportation. As noted earlier, this includes temperatures up to 130°F. Within this definition are materials otherwise not considered gases, but flammable liquids having a high vapor pressure when exposed to temperatures likely to be encountered in transportation. Of course, any flammable material not having a vapor pressure sufficiently high to meet the gas definition is regulated under the flammable liquids class.

Despite the fact that the section defines "compressed gas," this term is not itself a classification. A gas is classed either as a "Flammable gas" or "Non-flammable gas." Flammable gases are defined. All materials meeting the definition of a gas and that are not flammable are considered Nonflammable gases.

The flammable gas determination relates to the potential for forming a flammable mixture in air. For solutions of materials and gas, such as in aerosols, any one of three mandatory tests (described in Part 173.300(b)) might lead to a flammable gas classification: (1) having the material project a flame more than 18 inches beyond an ignition source with the container valve open fully, or with a flame flashing back and burning at the valve with any degree of valve opening, (2) having any significant propogation of flame away from the ignition source in the Bureau of Explosives open drum apparatus, or (3) having an explosion of the vapor air mixture using the Bureau of Explosives closed-drum apparatus. These tests and apparatus are described in documents available from the Bureau of Explosives.

The only significant difficulty in implementation of this definition relates to a lack of data involving vapor pressure curves of flammable liquids and other data on the properties of gases at various temperatures. While the classification is within the discretion of the shipper, the distinction between flammable and nonflammable gases makes heavy use of Bureau of Explosives testing methods, and the Bureau continues to be involved in this function.

POISONS

Materials regulated by DOT as poisons are those posing a very significant threat to human health when transported. Materials that might be regulated by other agencies because of toxic properties in the home or in the workplace are not necessarily reglated by DOT, since the hazard to the industrial transportation worker may not be present. Within the poison definition there are three classes: Poison A, Poison B, and Irritating materials.

Poison A is defined in 49 CFR 173.326 and, again, the definition is not really a definition at all. The section declares that Class A poisons are "Poisonous gases or liquids of such nature that a very small amount of the gas, or vapor of the liquid, mixed with air is dangerous to life." Like many of the DOT definition sections, the true definition is given by example rather than by quantitative criteria. In 49 CFR 173.326 there are eleven specifically named materials that are designated poisons, Class A.

Poisons that pose a lesser hazard are in the Poison B group, defined in 49 CFR 173.343 as, "Those substances, liquid or solid (including pastes and semi-solids), other than Class A poisons or irritating materials, which are known to be so toxic to man as to afford a hazard to health during transportation; or which, in the absence of adequate data on human toxicity, are presumed to be toxic to man because they fall within any one of (three prescribed) categories when tested on laboratory animals." The DOT definition thereafter gives the following quantitative test methodologies for determining oral, inhalation, and skin absorption toxicity:

> Oral Toxicity. Those which produce death within 48 hours in half or more than half of a group of 10 or more white laboratory rats weighing 200 to 300 grams at a single dose of 50 milligrams or less per kilogram of body weight, when administered orally.
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> Toxicity on inhalation. Those which produce death within 48 hours in half or more than half of a group of 10 or more white laboratory rats weighing 200 to 300 grams, when inhaled continuously for a period of one hour or less at a concentration of 2 milligrams or less per liter of vapor, mist, or dust, provided such concentration is likely to be encountered by man when the chemical product is used in any reasonable foreseeable manner.
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> Toxicity by skin absorption. Those which produce death within 48 hours in half or more than half of a group of 10 or more rabbits tested at a dosage of 200 milligrams or less per kilogram body weight, when administered by continuous contact with bare skin for 24 hours or less.

Once again, a paragraph is inserted in this definition to give regulatory flexibility to the Class B poison classification. This one reads: "The foregoing categories (of Class B poison descriptions) shall not apply if the physical characteristics or the probable hazards to humans as shown by experience indicate a substance will not cause serious illness or death. Neither the display of danger or warning labels pertaining to use nor the toxicity tests set forth above shall prejudice or inhibit the exemption of any substances form the provisions" of the DOT reguations. An example of material that may be relieved from regulation despite its technical inclusion within the Class B poison classification is one shipped in units so small that a hazardous dose for the most foreseeable human exposure never is present in a single shipment. In this instance, compliance of the full scope of regulations has been considered unwarranted, and regulation is not applied.

In contrast to similar paragraphs having to do with regulator flexibility, this paragraph does not appear to require the filing of any material with DOT, nor any form of DOT response. This paragraph gives discretion to the shipper of the material to determine whether his product is regulated or not, regardless of test results. Due to potential for civil liability, however, it is not believed that this mechanism has been used frequently by shippers of toxic materials without filing supportive documents with the agency.

An irritating material is defined in 40 CFR 173.381 as "A liquid or solid substance which upon contact with fire or when exposed to air gives off dangerous or intensely irritating fumes," such as certain specifically named materials but not including any Class A poisons. This is a very limited class dealing primarily with tear gas, chemical ammunition, and other materials infrequently encountered in transportation.

ETIOLOGIC AGENTS

An etiologic or disease-producing agent is defined by DOT as "A viable microorganism, or its toxin, which causes or may cause human disease." This definition is limited to specifically listed agents identified by the Department of Health and Human Services in 42 CFR 72..25(c). Etiologic agents were not regulated in transportation prior to 1960. Amendments to the Explosives and Other Dangerous Articles Act (18 USC 831-835) at that time specifically authorized direct regulation of such materials. DOT regulation of etiologic agents to date has not been substantive, but is a likely area for expansion in the future due to increased public concern with materials posing a threat to public health.

Although the etiologic agent definition includes many articles, the exceptions to substantive regulation tend to limit the scope of its applicability. Diagnostic specimens, biological products, and cultures of etiologic agents of 50 ml or less in a single outside package are fully relieved from regulation. As noted above, greater future regulation in transportation is anticipated.

RADIOACTIVE MATERIALS

In 49 CFR 173.389 of the DOT regulations, "radioactive material" is defined to mean "any material or combination of materials, which spontaneously emits ionizing radiation. Materials in which the estimated specific activity is not greater than 0.002 microcuries per gram of material, and in which the radioactivity is essentially uniformly distributed, are not considered to be radioactive materials." Within this classification, "fissile radioactive materials" are defined to include plutonium-238, plutonium-239, plutonium-241, uranium-233, asnd uranium-235, and any material containing any of these elements. Fissile radioactive materials are grouped into Classes I, II, and III, with Class III posing the greatest hazard in transportation.

"Large quantity radioactive materials" are defined by the amount of aggregate radioactivity of the material. "Low specific activity material" is defined as meaning any of a specified list of types of radioactive materials.

"Normal form radioactive material" means radioactive materials that are not "special form." Special form radioactive materials are those which, "if released from the package, might present some direct radiation hazard but would present little hazard due to radiotoxicity and little possibility of contamination."

The DOT rules on radioactive materials are essentially the same as those adopted by the International Atomic Energy Agency (IAEA). The definitions, other than the bare definition of radioactive materials quoted above, take the form of specifically named materials or activity levels.

Prior to amendment of the Explosives and Other Dangerous Articles Act in 1960, the Interstate Commerce Commission (now DOT) regulated radioactive materials as a Class D poison. The classification did not smoothly fit the nature of the hazard and authority was granted by Congress to clearly and directly regulate radioactive materials in transit.

The authority of the Department of Transportation significantly overlaps that of the Nuclear Regulatory Commission (NRC). This overlap is addressed in a longstanding memorandum of understanding between the two agencies. In general, while direct regulatory authority exists within DOT to govern these materials in transit, the designation function is performed by nuclear experts in NRC and in international regulatory bodies.

The regulation of radioactive materials is one of the few examples of DOT concern extending beyond the threat of immediate or acute damage from materials in transit. While long term health effects are not discussed in the DOT regulations, clearly these effects have been considered by the technical personnel in NRC and IAEA who have defined many of the terms and developed the regulatory concepts.

OTHER REGULATED MATERIAL (ORM)

An "Other Regulated Material" is any material that does not meet the definition of a hazardous material, other than a combustible liquid in packagings having a capacity of 110 gallons or less, and is specified (in 49 CFR 172.101) as an ORM material or that possesses one or more of the characteristics described" in the ORM-A, B, C, D, or E classifications.

Most of the ORM classifications were created in Docket No. HM-112 in 1976. The classifications were to accomodate the historical nature of the DOT system which requires a class before materials may be regulated. Since all other classes are devoted to specific general hazards, there was a need for miscellaneous hazard classes. For the most part, these hazards are not general in nature but are specific to given modes of transportation. In other words, a material that is harmless in one mode but dangerous in another, such as an aluminum-corrosive liquid, is regulated in an ORM class so impact of the regulation can be focused on the mode in question. Being a miscellaneous hazard aggregation, the ORM classifications are readily susceptible to expansion, as evidenced by recent creation of the ORM-E class.

The suffix letters of the ORM classes do not convey any meaning, but are merely in alphabetical sequence. In other words, the ORM-E class having to do wtih environmental hazards has no correlation with the fact that "environment" begins with the letter "e." It was merely the designation next in line after ORM-D.

ORM-A is a material which "has an anesthetic, irritating, noxious, toxic, or other similar property which can cause extreme annoyance or discomfort to passengers and crew in the event of leakage during transportation." These materials are particularly hazardous in a cargo transportation unit that also encloses people, passengers or crew, such as a vessel or an aircraft. ORM-A materials, therefore, are almost never subject to regulation in truck or rail transport, unless they are being regulated because of their environmental impact as hazardous substances, or as hazardous wastes defined under Section 3001 of RCRA.

The majority of materials in the ORM-A classification would impair breathing or vision and are take from a similar list of materials that have been regulated for years in the international air transportation field by IATA (International Air Transport Association). Under the IATA regulations, these materials were called ORA (Other Regulated Articles). Some materials formerly listed by the Coast Guard as hazardous articles also have come into the ORM-A class. In Docket No. HM-112, DOT examied all such IATA and Coast Guard regulated materials for their hazard potential in air or water transportation. Not all listings were adopted by DOT. Those included in the ORM-A classification are specifically listed by name in 49 CFR 173.605 throgh 173.655, or fall within an "ORM-A, n.o.s." shipping description. ORM-A, n.o.s., items are not specifically listed but pose the type of hazard described in the basic ORM-A definition. The ORM-A definition is highly subjective and depends heavily on the judgment and caution of the shipper rather than on quantitative criteria.

ORM-B is another classification adopted in the HM-112 rulemaking. An ORM-B is defined in 49 CFR 173.500 as a "material (including a solid, when wet with water) capable of causing significant damage to a transport vehicle or vessel from leakage during transportation." Materials in the ORM-B class are either specifically designated by chemical name in the alphabetical table in 49 CFR 172.101, or fall within the class based upon the results of a given NACE aluminium-corrosion test. If a liquid has a corrosion rate in excess of 0.250 inches per year on aluminum under this test, and exhibits no other regulated hazards, it falls within the ORM-B classification. This classification generally is limited to substantive restrictions in air transportation (although some also are regulated by water) and is keyed directly to the potential to damage to the aircraft or vessel if the material were to spill and attack aluminum structural members. While the concern in this designation is protection of property, it is a property-protective concern linked directy to safety, since destruction of any structural member of an aircraft or vessel has an obvious safety impact.

An ORM-C is a "material which has other inherent characteristics not described as an ORM-A or ORM-B, but which made it unsuitable for shipment, unless properly identified and prepared for transportation. Each ORM-C material is specifically named in 49 CFR 172.101 of the DOT regulations. This classification does not have an n.o.s. shipping name. As noted in the definition, it is limited to articles specifically named in the DOT regulations. To a large extent, these materials had been regulated under Coast Guard authority under the term "hazardous articles." Understandable confusion between the terms "hazardous materials" and "hazardous articles" was one of the reasons for changing the name of the latter.

One of the purposes of Docket No. HM-112 was to bring air, water, and land transportation regulations into a single volume of the Code of Federal Regulations. The air rules had appeared in Title 14, the water rules in Title 46, and the rail and highway rules in Title 49 CFR. Upon consolidation of all modes into Title 49, with certain exceptions air-regulated materials became ORM-A's, and water-regulated material became ORM-B's and ORM-C's.

The hazard common to most ORM-C entries is spontaneous combustion. In other words, these are solid materials such as vegetable fibers, tankage, metal borings, and oiled material that have a strong potential for spontaneous heating and ignition, and when enclosed in a vessel in bulk in the presence of humidity. In other modes of transportation, unit quantities are smaller and the environment is different and does not warrant the regulation of ORM-C materials. Generally speaking these materials are regulated only in the water mode. An ORM-C regulated only in air transport, however, is magnetized material. An exception to these modal limitations occurs if an ORM-C material also is a hazardous substance or hazardous waste under RCRA definitions. In that case, it is regulated in all modes of transportation because of its environmental hazard, but is regulated under the ORM-C classification.

ORM-D is a novel entry in the DOT regulations. This classification did not, in fact, have a predecessor class but is a new grouping of materials created in the Docket HM-112 rulemaking. An ORM-D is defined in 49 CFR 173.500 as, "A material such as a consumer commodity which, though otherwise subject to the regulations of this subchapter, presents a limited hazard during transportation due to its form, quantity or packaging." In other words, products in the ORM-D class are those which fall within definitions or other general DOT classifications, but do not warrant substantive regulation. The strong contention that these materials may not warrant any regulation has never been fully answered by the Department of Transportation.

The only articles currently in the new ORM-D classification are consumer commodities. "Consumer commodity" is defined in 49 CFR 171.8 as, "A material that is packaged and distributed in a form intended or suitable for sale through retail sales agencies or instrumentalities for consumption by individuals for purposes of personal care or household use. This term also includes drugs and medicines." While the ORM-D classification is not structurally limited to consumer commodities, at this time these are the only materials within the classification.

Not every consumer product falls within the classification. The consumer product must be one for which general exceptions (i.e., small quantity exclusions) are permitted as listed in 49 CFR 172.101. It also must be within packaging limitations for the consumer market as well as specific quantity limits and packaging types prescribed in 49 CFR 173.1200.

An article is reviewed first by its shipper for its hazard, for example, flammability. If, for example, the article is (1) a flammable liquid, (2) a consumer commodity (as defined), (3) is granted exceptions due to its small size in various "limited quantity" paragraphs of the regulations (e.g. 49 CFR 173.118(d)), and (4) is in specifically described packages less than 65 lbs. gross weight, it may be _re_classified from the Flammable liquid class into the ORM-D class. ORM-D in effect, is a secondary classification for materials that primarily meet basic definitions but, due to small size packaging and regulation imposed by other agencies (such as the Consumer Product Safety Commission), need not be subjected to substantive DOT regulation in transportation. Most general DOT regulations do _not_ apply to ORM-D materials and, to the extent there is regulation, it is distinctly related to air transportation, not other modes.

HAZARDOUS WASTES, HAZARDOUS SUBSTANCES, AND ORM-E

Hazardous wastes are defined by EPA under Section 3001 of the Resource and Conservation Recovery Act. EPA definitions implementing Section 3001 appear in 40 CFR Part 261. It is clear from the statement of Congressional interest in passage of RCRA that control of hazardous wastes in transportation was envisioned, and that the EPA requirements on such transportation should be consistent with those adopted by the Department of Transportation. Implementing this intent, DOT in conjunction with EPA proposed regulation of hazardous wastes in transportation in DOT Docket No. HM-145A. After a significant comment period, Docket Nos. HM-145A on hazardous wastes and 145B on hazardous substances were adopted by the Department of Transportation on May 22, 1980 (45 FR 34560).

With the administrative determination that DOT would administer the transportation regulations for hazardous wastes defined by EPA, it was necessary to create a mechanism for this regulation. To simply establish a new classification would have been unduly confusing, since many EPA-designated wastes already were covered by the DOT regulations. Basically the approach followed by DOT in their rulemaking was to overlay the DOT regulations with the EPA definition. As a result, for example, any flammable liquid that was already regulated by DOT continues to be regulated in the flammable liquid class, but its properties as a waste are highlighted by container markings and by the waste manifest.

Because definitions applied by both agencies are not identical, there are places where the EPA regulations apply and no DOT rules were in place. In overlaying the DOT classes with the EPA waste definition, there was extension beyond the purview of the existing DOT rules at certain points For those materials in this extended area that were unregulated prior to HM-145, DOT created a new classification--ORM-E. This classification is discussed more fully below but, in short, is made up of articles that are environmentally threatening, but that do not pose a safety threat in transportation under traditional DOT definitions.

Hazardous substances are also regulated by DOT now. This was an effort undertaken in Docket No. HM-145B. Amendments adopting hazardous waste and hazardous substance rules were developed concurrently and consequently are somewhat coordinated. Like hazardous wastes, the list of approximately 300 hazardous substances developed by EPA under Section 311(b) of the Clean Water Act included many items already regulated by DOT for their safety hazards. Materials in all of the traditional classifications as well as many in the ORM-A, B, C and D classes were designated as hazardous substancs by the EPA.

For practicality, DOT adapted EPA's definition of hazardous substance to fit transportation principles. Under new 49 CFR 171.8, "hazardous substance" for DOT purposes "means a quantity of material offered for transportation in one package, or transport vehicle when the material is not packaged, that -- (a) equals or exceeds the reportable quantity (RQ) specified for the material in EPA regulations at 40 CFR Parts 116 and 117; (b) is identified by the letter "E" in column 1 of Part 172.101; and when in a mixture or solution in any package offered for transportation is in a concentration which equals or exceeds the following (based on the RQ weight quantities specified in 49 CFR 172.101):

RQ Pounds	RQ Kilograms	Concentration by Weight Percent	Concentration by Weight PPM
5000	2270	10	100,000
1000	454	2	20,000
100	45.4	0.2	2,000
10	4.54	0.02	200
1	0.45	0.002	20

The key element of this definition is that, at a minimum, one does not have a hazardous substance until the reportable quantity for that substance is contained within a single package. By this mechanism, DOT avoids the applicability of unnecessary regulation to trace amounts of hazardous substances that may be present but not in significant amounts. Whereas it is theoretically conceivable that trace amounts of hazardous substances in a full transportation unit, dumped in its entirety in a navigable waterway, might in the aggregate reach a reportable quantity threshold for reporting under the Clean Water Act, DOT found that practical experience in transportation accidents made this circumstance unlikely. It is not impossible, but the extreme burden upon transportation carriers in particular, who would have to arithematically aggregate all trace quantities on one vehicle before moving, was not felt worthwhile in light of the goals to be achieved. In a subsequent Federal Register publication, EPA concurred in this interpretation of the Clean Water Act for transportation purposes (45 FR 61617).

As with the hazardous waste definition, the hazardous substance definition developed by DOT was laid over the classifications traditionally contained in the Hazardous Materials Regulations. Requirements for materials already regulated by DOT by name were adjusted to include a reference to the reportable quantity (RQ), to appear on shipping documents and package markings. Requirements for materials regulated by DOT but not by their chemical names were modified so documents and package marking would include the EPA-listed name. Rules applicable to materials in the ORM-A, B, C and D classifications were modified so that a material that is a hazardous substance or a hazardous waste is regulated in all modes of transportation, regardless of the fact that in its non-hazardous substance or non-waste form it is only regulated in air or water commerce. An ORM-A, for example, that is covered by the hazardous substance definition now is regulated as an ORM-A in all modes of transportation and must be marked and documented as an ORM-A hazardous substance.

As with the hazardous waste definition, the hazardous substance definition did not fit neatly over the DOT regulated materials. There were several materials that did not fit any historic DOT hazard definitions. For these DOT has assigned the ORM-E classification. This is the same class applied to hazardous wastes that do not meet another DOT definition. ORM-E as a new classificaton is discussed more fully below.

It will be noted that the hazardous substance definition makes reference to the letter "E" appearing in column 1 of 49 CFR 172.101. Use of this letter conveys only the correlation between the word "environment," which begins with that letter, and has no direct relation to the ORM-E classification. Not every item so noted fits the ORM-E class, nor is every item so noted necessarily a hazardous substance if the RQ qualifications are not met. The letter "E" is merely a signal that environmental rules may apply, not that they necessarily do apply. It is a signal to the reader to look further.

ORM-E is a very recent addition to the DOT list of classifications. It was adopted in Docket No. HM-145A, published in the Federal Register of May 22, 1980 (45 FR 34560). Under the new amendments, an ORM-E is a material subject to DOT regulation that is not included in any other DOT hazard class. Materials in the ORM-E class now include hazardous wastes (as defined by EPA under Section 3001 of RCRA) and hazardous substances (as designed by EPA but defined by DOT in 49 CFR 171.8 of the DOT Regulations). The class is structured to accommodate more materials in the future, e.g., materials regulated under Superfund, P.L. 96-510.

Creation of the ORM-E class and other hazarous waste and substance regulations adopted in Docket Nos. HM-145A and 145B are the first clear entry by DOT into regulation of materials that are environmentally hazardous, but that may not pose direct threats to people or transportation property. A question of the agency's authority under the HMTA to issue such regulations was raised in comments on Docket No. HM-145B. The answer of th agency, published on May 22, read: "The pertinent language in Section 311 of the Clean Water Act (33 USC 1321), EPA's authority for designating hazardous substances, is contained in paragraph (b)(4), which provides for determination of 'those quantities of ... any hazardous substances the discharge of which may be harmful to the public health or welfare...." Clearly, many of the risks involved in the transportation of hazardous materials relate to the possibility of unintentional release, and such releases may involve discharges into the navigable waters of the United States. To the extent that EPA has designated certain substances in specific quantities as potentially harmful, it is appropriate for (the Materials Transportation Bureau) to designate those quantities of those materials as hazardous materials under the HMTA. Moreover, should MTB not take this action, it would be left to EPA to fill the void covering the transportation of those hazardous substances not reached by DOT regulations. Such a split in regulatory coverage would be inefficient and a hinderance to all concerned." (43 FR 34369)

DOT's response to the issue of their authority does nothing to dispel the contention that there was uncertain basis in the HMTA, at the time these rules were adopted, for DOT to regulate environmentally hazardous substances. The designation criteria under the Clean Water Act and the HMTA are totally different. The claim of authority based on administrative efficiency carries little legal weight. A hazardous material in the DOT statute is defined as one posing an unreasonable risk to health or safety and property, and that definition has not been changed by Congress.

The Comprehensive Environmental Reponse Compensation and Liability Act of 1980 (Superfund), Public Law 96-510, was signed by the President on December 11, 1980.[1] Section 306(a) of this Act compels the Secretary of Transportation to list as a hazardous material under the HMTA, any material designated as a hazardous substance in the new statute. The term hazardous substance in the new statute, of course, includes more than merely Section 311(b) Clean Water Act materials customarily described by that term. The term now includes water pollutants, air pollutants, materials receiving attention under TSCA, hazardous wastes, and other materials that might later be designated as hazardous substances by the Administrator of EPA. Listing a hazardous substance in the DOT regulations for purposes of documentation and notice, however, may not be the same as an alteration of the HMTA statutory definition of hazardous material. The order in Superfund for DOT to list EPA-designed hazardous substances does not necessarily give DOT the direct authority to initiate the designation of materials that endanger the environment, but pose no direct threat to human health or safety or commercial property in transportation, as a hazardous materials. In other words, the HMTA statutory criteria remain unaffected by the Superfund Act.

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[1] See statutory review included in Volume II.

SUMMARY

In conclusion, under the HMTA the Department of Transportation has clear authority to designate materials as hazardous when transported in commerce. That authority has not been used, except in rare instances, to designate new materials. Rather, DOT used its authority to take materials designated under a predecessor statute in a blanket adoption of those designations and requirements for those materials as "new law" regulations. (Docket No. HM-134, 41 FR 38175, Sept. 9, 1976.)

There is no established mechanism or quantitative basis upon which DOT acts in designation of materials. The materials must be classed before being regulated, and the classes themselves are ambiguous, subjective, inconsistent, and not susceptible to ready definition or quantification. There is no basic mission statement or policy position guiding the agency or the public on DOT actions under the HMTA. The process is subjective and informal and must be viewed with a certain degree of skepticism by those who would prefer a quantitative, consistent approach to controls.

The primary value of the DOT system is that it is there, and within its context it is familiar to people who are regulated by it. Without question, the early thrust of regulation of materials in transit dealt with the acute hazard potential of the materials. Now that DOT has embarked on the designation (or at least the listing) of materials that pose environmental hazards or long term health hazards, it is unclear what limit there is to the HMTA authority.

U.S. COAST GUARD--REGULATORY REVIEW

As noted in the Statutory Review, the Dangerous Cargo Act, 46 USC § 170, was developed to augment the statutory authority in the Explosives and Other Dangerous Articles Act, 18 USC § 831-835. The latter statute applied to shippers by all modes including water, but needed to be statutorily extended to water carriers. The authority under the Dangerous Cargo Act is exercised by the United States Coast Guard, a part of the Department of Transportation.

The Dangerous Cargo Act required the Coast Guard, in exercising this authority, to accept and adopt the "definitions, descriptions, descriptive names and classifications" adopted under the Explosives and Other Dangerous Articles Act. Those designations of hazardous materials now occur under the successor statute, the Hazardous Materials Transportation Act, implemented by the Department of Transportation with input from the Coast Guard.

In DOT's rulemaking Docket No. HM-112, completed in 1976, regulations applicable to water transportation of most packaged hazardous materials were relocated from 46 CFR into 49 CFR Part 176. Many of the provisions unique to water transportation were removed to that Part and also are reflected in the creation of the ORM-A, ORM-B and ORM-C classifications discussed in the HMTA regulatory review. Not all Coast Guard regulations of materials, however, are addressed in Title 49. The Dangerous Cargo Act still supports regulations appearing elsewhere in the Code of Federal Regulations. These and other Coast Guard regulations dealing with hazardous substances are discussed below.

MILITARY EXPLOSIVES

One active area appears in 46 CFR Part 146 entitled, "Transportation or storage of military explosives on board vessels." In Subpart 146.20, the Coast Guard sets out detailed regulations governing explosives. Explosives here are defined as they are in Title 49.

This coincidence of classification definition, however, is somewhat misleading in the regulations on handling military explosives. It was found that the commercial regulations for ocean shipment of explosives and other hazardous materials were too restrictive for vessels that were devoted to transportation of ammunition, such as those operated for the military. The 49 CFR regulations simply do not provide enough alternatives for the loading and stowage of explosives to satisfy the needs of a vessel for military explosives.

Consequently, in 46 CFR 146.29-100, there is an entirely different system of "classification" of explosives. These classifications are for the purpose of segregating materials to assure compatibility and to designate stowage locations aboard ammunition-carrying vessels. Thus, for example, one finds Class I made up of small arms ammunition (without explosive bullets), denotating fuses, DOT Class C mechanical time fuses, and like items. Class

II-A is made up of bulk propellants such as ballistite, cordite, propellant charges, and "made-up" bag charges in outside shipping containers. Class IV includes fixed and semi-fixed ammunition with explosive loading projectiles. Class VIII includes various mine fuses, blasting caps and detonators. Class X-C includes guided missiles and solid propellant motors packed with or without wareheads. Class XI-B includes non-lethal chemical ammunition. Class XI-D covers oxidizers in containers for guided missiles and rockets.

These various reclassifications, done for the sake of specialized military transportation, may or may not be consistent with the original Class A, B and C classifications developed in Title 49 and referenced in Title 46. One finds A, B and C explosives all included in several of the military classifications. In Class XI-D mentioned above, the "oxidizers" are classed under Title 49 as corrosive liquids, non flammable gases and oxidizing materials without any of them being classed as Title 49 explosives for commercial purposes.

This is an esoteric area of classification developed for the specialized use of military shipments of ammunition. It is oriented toward the loading and stowage of materials to minimize incidents in transportation where the vessel is filled with a variety of explosives. Because of its limited applicability, it is not discussed in greater depth.

SHIPS' STORE AND SUPPLIES

Part 170 of 46 USC authorizes the Coast Guard to develop regulations to control the use of hazardous materials aboard vessels. These regulations are published in 46 CFR Part 147 and are entitled, "Regulations governing use of dangerous articles as ships' stores and supplies on board vessels."

Ships' stores and supplies are defined in 46 CFR 147.02-1 as "any article or substance which is used on board a vessel subject to the regulations of (the Coast Guard) for the upkeep and maintenance of the vessel; or for the safety or comfort of the vessel, its passengers or crew; or for the operations or navigation of the vessel (except fuel for its own machinery); except shipboard fumigation" regulated elsewhere. 46 CFR 147.02-2 defines ships' stores "of a dangerous nature." For the purpose of these regulations, materials with "such characteristics properties as will cause the substance to properly classify as either an explosive, inflammable liquid, inflammable solid, oxidizing material, corrosive liquid, compressed gas, poisonous article, hazardous article or combustible liquid in accordance with the definitions for such substance as contained in the regulations in this subchapter are defined as ships' stores and supplies of a dangerous nature."

Because of a series of rulemaking actions elsewhere over the past few years, this definition is incomprehensible. For example, at the latter portion of the quote where it speaks of definitions of substances as contained "in this subchapter," one finds there are no such definitions in the subchapter containing these regulations today. This is a vestigial reference to a series of definitions moved to Title 49 in 1976. The words inflammable liquid and solid are now outdated. In Title 49, oxidizing materials are called oxidizers. "Hazardous articles" are those that became ORM-A, ORM-B or ORM-C in Title 49. Combustible liquids at the time this regulation was developed meant liquids with a flash point of 80°F. to 150°F, whereas today in Title 49 that definition begins at 100°F. and goes up to 200°F. There is no reference whatsoever to the new ORM classifications. In short, the regulations on ships' stores and supplies are fatally defective and give little illustration of what is required.

In practice, it is understood that these rules apply to all articles classed as hazardous material in Title 49. This is not written anywhere. It is merely known in the regulated community and by the Coast Guard.

These regulations are more akin to occupational safety and health rules than to hazardous materials transportation rules. The reference to the DOT regulations, therefore, perhaps indicates a deficiency in these rules. There are many hazards encountered in the use of a product that are not present in transportation and, therefore, are not addressed in the DOT rules in 49 CFR.

The handling of various regulated materials that do not need to be specially "certificated" or approved by the Coast Guard is addressed in 46 CFR 147.05-100. The materials are described and by their various properties are limited in use. These properties may or may not coincide with elements of the 49 CFR classifications. For example, the definition of combustible liquid in 49 CFR extends from 100° to 200°F. End use regulations in Title 46, however, often refer to goods with flash points of 150°F. Hazardous materials not covered by this table are intended to be identified as in 49 CFR 172.101 and require special Coast Guard certification before they may be used on board vessels. Some materials are not permitted for use, but this is not written in the regulations.

BULK SOLID HAZARDOUS MATERIALS BY VESSEL

The Dangerous Cargo Act includes authority for the Coast Guard to regulate shipments of bulk solid hazardous materials by vessel. Section 170(6)(a) of the statute prohibits transportation of bulk solid hazardous materials on board any vessel unless authorized by Coast Guard regulation or other special authorization. The term "hazardous materials" for these purposes is defined in 46 CFR 148.01-1 to mean hazardous materials as defined in 49 CFR Parts 170-89. Materials listed in Section 148.01-7 by the Coast Guard as authorized for carriage include a variety of flammable solids, oxidizing materials and ORM materials, as well as low specific activity radioactive materials. In addition to the specific listed articles permitted by regulation, there is a procedure for seeking special permission to carry bulk solids. This exemption procedure is outlined in 46 CFR 148.01-9 and 158.01-11.

BULK LIQUID DANGEROUS CARGOES BY VESSEL

Coast Guard regulation of hazardous materials in bulk tankers and barges occurs under rules commonly referenced as Subchapter D and Subchapter O regulations. Subchapter D, made up of Parts 30-40 of 46 CFR, addresses liquids and liquefied gases bearing the hazards of flammability or combustibility, but without additional hazards. Generally these are hydrocarbons. Subchapter O, made up of 46 CFR 151-154, addresses chemical bearing other hazards that may include flammability and combustibility as well. Each Subchapter prescribes requirements, but there is heavy cross-referencing between Subchapters for definitions and other requirements.

Within Subchapter D, Part 30 contains general requirements; Part 31, general inspection and certification rules for tankers; Part 32, special equipment, machinery, and hull requirements; Part 33, lifesaving equipment; Part 34, firefighting equipment; Part 35, tanker operations; Part 36, elevated temperature cargoes; Part 37, special construction, arrangement and other provisions for nuclear vessels carrying flammable or combustible cargo; Part 38, liquefied and compressed flammable gases; and, Part 40, special construction arrangement, and other provisions for carrying vinyl chloride in bulk.

Within Subchapter O, Part 151 addresses unmanned barges carrying certain bulk dangerous cargoes; Part 153, safety rules for self-propelled vessels carrying hazardous liquids; and Part 154, safety standards for self-propelled vessels carrying bulk liquefied gases.

Regulations on unmanned barges are issued by the Coast Guard under the authority of the Dangerous Cargo Act, 46 USC 170, as well as 46 USC 391a. The unmanned barge regulations are set forth in 46 CFR Part 151 and contain uniform minimum requirements for transportation of liquids or liquefied gases in bulk (other than flammables and combustibles regulated under Subchapter D), including materials not regulated under the HMTA.

As with the regulations in ships' stores and supplies, the regulations on unmanned barges also suffer from inconsistencies and inaccuracies related to rulemaking changes elsewhere. For example, in 46 CFR 151.01-1 there are lists of cargoes affected by these regulations and the list includes hazardous articles now properly classified as ORM-A, B and C materials. There are many sectional cross-references to regulations that no longer exist -- predecessors to hazard definitions now appearing in 49 CFR. The requirements on unmanned barges do not involve the designation of hazards, but cross-reference designations made elsewhere in 46 CFR and in 49 CFR.

Coast Guard regulations in 46 CFR Part 153 on bulk chemicals aboard self-propelled vessels, issued jointly under 46 USC 170 and 391a, also adopt the hazardous materials classification definitions published in 49 CFR. An exception to this are definitions of flammable and combustible liquids that appear in 46 CFR 153.2. There, a flammable liquid is defined as it is in Subchapter D, in 46 CFR 30.10-22, and a combustible liquid as it is defined in 30.10-15.

The referenced definition sections are published as part of the Subchapter D. The definitions in Subchapter D predate changes that took place in HM-102 and continue to draw distinctions and limitations from that earlier period. These are the definitions applicable to bulk tankers (including manned and unmanned barges). 46 CFR 30.10-22 defines a flammable liquid as, "any liquid which gives off flammable vapors (as determined by flash point from an open cup tester as used for test of burning oils) at or below a temperature of 80°F." Flammable liquids are referred to by grades as follows: (a) Grade A, any flammable liquid having a Reiad vapor pressure of 14 lbs. or more; (b) Grade B, any flammable liquid having a Reid vapor pressure under 14 lbs. and over 8-1/2 lbs.; and (c) Grade C, any flammable liquid having a Reid vapor pressure of 8-1/2 lbs. or less and a flash point of 80°F. or below.

46 CFR 30.10-15 defined combustible liquid to mean, "any liquid having a flash point above 80°F. (as determined from an open cup tester, as used by test of burning oil)." In Subchapter D, combustible liquids also are referred to by grades, as follows: Grade D, any combustible liquid having a flash point below 150°F. and above 80°F.; and Grade E, any combustible liquid having a flash point of 150°F. or above.

The flammable liquid definition here stops at 80° F., as it used to for land regulations before Docket No. HM-102 changes. The combustible liquid definition is interesting because of the classficication of combustibles below 150°F., rather than 200°F. as in 49 CFR. Even more importantly, regulation as a combustible liquid occurs with any material with a flash point from 150°F. to infinity. This means, for example, that molasses in a bulk tanker is shipped as a combustible liquid.

Materials listed in Parts 30 and 153 may be carried in bulk (when the vessel is certificated for such carriage by the Coast Guard) as long as the published rules are met. Materials not listed by name in either part must be made the subject of a special application for a Coast Guard certificate, in order to be carried in bulk aboard any self-propelled vessel or tank ship. There are no published criteria upon which such a certificate is granted or denied.

Coast Guard rules on self-propelled vessels carrying bulk liquefied gases are issued under the authority of 46 USC 391a, and are published in 46 CFR Part 154. In 46 CFR 154.3, a liquefied gas is defined as a cargo having a vapor pressure of 25 psi or more at 37.8°C. (100°F.). The regulations provide for carriage of specific listed gases. This list was developed over time from known gases for which a great need was felt or gases that were specifically requested by individual applicants to be moved in bulk vessel operations. The list is in Table 4 of Part 154.

The term "flammable cargoes" is defined in 46 CFR 154.3 as including the following gases from Table 4:

- Acetaldehyde
- Butadiene
- Butane
- Butylene
- Dimethylamine
- Ethane
- Ethylamine
- Ethyl chloride
- Ethylene
- Ethylene oxide
- Methane (LNG)
- Methyl acetylene-propadiene mixture
- Methyl bromide
- Methyl chloride
- Propane
- Propylene
- Vinyl chloride

"Toxic cargoes" are defined to mean the following liquefied gases from Table 4.

- Acetaldehyde
- Anhydrous ammonia
- Dimethylamine
- Ethylamine
- Ethyl chloride
- Ethylene oxide
- Methyl bromide
- Methyl chloride
- Sulfur dioxide
- Vinyl chloride

Materials regulated in bulk include all those falling within the definition of a hazardous material as well as other combustible liquids. For the shipment of a hazardous material or a mixture of hazardous materials that is not authorized specifically by name in these various parts of Title 46, it is necessary to go through a special approval process before the vessel may be certificated by the Coast Guard to carry the material. The process may or may not result in the issuance of a certificate. Generally speaking the applicant for certification is subjected to a variety of requirements that are keyed to the given material. It has occurred, however, that certification has been denied for materials too dangerous to be carried in bulk. There is no assurance that the conditions attached to issuance of a certificate would be within the realm of economic feasibility. It does not appear that in making these determinations, the Coast Guard uses any published criteria. Each decision is a case unto itself, and decisions are made on an application-by-application basis.

DANGEROUS CARGOES ON WATERFRONT FACILITIES

Under the Ports and Waterways Safety Act, 33 USC § 1225, the Coast Guard has issued regulations published in 33 CFR 126 pertaining to the handling of explosives or other dangerous cargoes within or contiguous to waterfront facilities. 46 CFR 126.07 defines dangerous cargo to mean all explosives and other hazardous materials or cargo covered by regulations of the Coast Guard in 46 CFR 33-38, 146, and 148. In addition, the definition includes hazardous materials except those preceded by an "A" in Title 49 CFR Parts 170-179. Those preceded by an "A" in the hazardous materials table, of course, are only regulated by air (unless they are hazardous wastes or hazardous substances).

33 CFR 126.10 lists "cargo of particular hazard", noting those of high hazard such as explosives and others that pose a significant danger in bulk quantities. Under these regulations, the primary concern is the safety of the waterfront facility. Judging by the materials regulated under Part 126, it is clear that the acute injury potential caused by fire and explosion are the primary concerns in establishment of these regulations. The mechanism of control is the issuance of permits to people engaged in activities involving hazardous materials coming to or being held at waterfront facilities.

FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration is responsible for the implementation of several statutes authorizing the regulation of chemical substances, including:

Federal Food, Drug, and Cosmetic Act
Pesticide Chemical Act
Food Additives Amendment
Color Additives Amendment
Drug Amendments
Animal Drug Amendments
Medical Devices Amendments

The legal reviews and regulatory analyses that follow do not necessarily represent the official position of the FDA or the Department of Health and Human Services. Moreover, this material has not been officially endorsed by the EPA as its understanding of FDA authority.

The FDA statutory and regulatory reviews focus on the health and safety aspects of FDA authority and do not consider the FDA's powers with respect to product efficacy, standards of product purity, accuracy in labeling and other issues apart from the regulation of risks to health and safety posed by chemical substances.

FOOD, DRUG, AND COSMETIC ACT OF 1938 AND MAJOR AMENDMENTS -- STATUTORY REVIEW

FOOD, DRUG, AND COSMETIC ACT OF 1938

Responding to increasing public awareness and growing political pressure, Congress passed the landmark Pure Food and Drug Act in 1906.[1] The bill aimed to protect consumers and to insure the purity of their purchases by prohibiting the sale of adulterated or misbranded foods and drugs. By 1938, however, changing conditions had made the bill obsolete. Moving to revitalize consumer protection in the area, Congress replaced the old law with the Federal Food, Drug, and Cosmetic Act (FDCA).[2]

The new Act retained most features of the older legislation but greatly expanded its scope. For example, coverage was extended to cosmetics[3] and therapeutic devices[4] (medical devices) for the first time. The Act also stipulated that drug manufacturers had to prove that their new products were safe before they could be marketed.[5] In addition, the legislation increased government's enforcement powers by authorizing factory inspections,[6] requiring companies to maintain records of interstate shipments,[7] and empowering courts to enjoin violations.[8]

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[1] June 30, 1906, ch. 3915, 34 Stat. 768.

[2] June 25, 1938, ch. 675, 52 Stat. 1040, codified as 21 USC §301 et seq. When it was passed, the FDCA was statutorily administered by the Secretary of Agriculture. By regulation, however, administration of the law was transferred within the Department to the Food and Drug Administration (FDA). In 1940, the FDA was transferred to the Federal Security Agency, and in 1953 to HEW. With the creation of the Department of Education in 1980, HEW was renamed the Department of Health and Human Services. Over time, actual administrative authority has remained with the FDA. For simplicity, the statutory analysis will use the word "Secretary" instead of identifying the particular Secretary and Department which had authority at any one time.

[3] 21 USC §§ 361-363.

[4] 21 USC § 351 et seq.

[5] 21 USC § 355.

[6] 21 USC § 374.

[7] 21 USC § 373.

[8] 21 USC § 332.

In another major step, the FDCA provided that an added "poisonous or deleterious substance" could be safely present in foods under carefully regulated conditions.[9] Previously, any food containing an "added poisonous or deleterious substance" was automatically considered "adulterated"--even if the concentration of the substance was so small that the Secretary believed that no health hazard existed. The FDCA moved away from this absolute approach. Instead, it allowed the Secretary to permit a specified tolerance of a deleterious substance in a food if (a) it was required in production or could not be removed by good manufacturing procedures, and (b) it did not exceed a level that endangered public health. This provision was Congress' first recognition that a potentially toxic substance may be safely consumed in small, carefully regulated concentrations. The idea is now widely applied throughout the Act; the Secretary may approve the use of most chemicals as long as they are safe for intended use. In fact, when approving most types of substances, the Secretary must specify the conditions under which they may be safely used.

Since 1938, the basic FDCA has been substantially augmented. Major amendments have extended government control over food and color additives,[10] pesticide chemicals on raw agricultural commodities,[11] drugs and animal drugs,[12] and medical devices.[13] Those amendments, outlined in Exhibit 3-1, contain the Food and Drug Administration's (FDA) primary powers to identify and regulate toxic and potentially toxic substances. Following a discussion of the definition of hazard and the general mandatory reporting requirements specified in the FDCA, the major amendments to the statute will be examined.

Statutory Criteria for Regulation and Factors for Regulation

The FDCA regulates the safety of foods, drugs, medical devices, and cosmetics. Potentially toxic chemicals specifically covered include any "food additive," "color additive," "drug," "animal drug," "pesticide chemical in or on raw agricultural commodities," and any "poisonous or deleterious substance" in foods, drugs, medical devices, or cosmetics. Statutory provisions relating to each of these substances, summarized in Exhibit 3-2, will be carefully explored below and in the following sections. The regulation of efficacy of drugs, product purity, and the like, is not considered in this review.

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[9] 21 USC § 346.

[10] Sept. 6, 1958, Pub. L. No. 85-929, 72 Stat. 1784; July 12, 1960, Pub. L. No. 86-618, 74 Stat. 399.

[11] July 22, 1954, ch. 559, 68 Stat. 511; July 12, 1960, Pub. L. No. 86-618, 74 Stat. 397.

[12] Oct. 10, 1962, Pub. L. No. 87-781, 76 Stat. 781-783, 784, 785, 796; July 13, 1968, Pub. L. No. 90-399, 82 Stat. 343,351; Oct. 24, 1968, Pub. L. No. 90-639, 82 Stat. 1361, 1362.

[13] May 28, 1976, Pub. L. No. 94-295, 90 Stat. 575.

EXHIBIT 3-1

THE FOOD, DRUG, AND COSMETIC ACT AND MAJOR AMENDMENTS

Act or Amendment	Year Enacted
Food, Drug, and Cosmetic Act	1938
Pesticide Chemical Act	1954
Food Additives Amendment	1958
Color Additive Amendment	1960
Drug Amendments	1962
Animal Drug Amendments	1968
Medical Devices Amendments	1976

EXHIBIT 3-2

SELECTED PROVISIONS OF THE FDCA

Substance	Prohibited if Adulterated or Unsafe	Premarketing Approval Required	Mandatory Reporting	Delaney Clause
Pesticide Chemical on Raw Food Commodity	X	X	O	O
Food Additive	X	X	O	X
Color Additive	X	X	O	X
Cosmetic	X	O	O	O
New Drug	X	X	X	O
New Animal Drug	X	X	X	X
Medical Device	X	X (some)	X	O

X = Required
O = Not required

The FDCA takes an extremely cautious approach toward the identification and regulation of potentially toxic substances. In general, new substances covered by the Act are presumed to be unsafe and are prohibited from interstate commerce unless the Secretary has approved and not withdrawn approval of the use of the substance. Examples include approval of a new drug application (NDA), an investigational new drug (IND) notice and certification or release of drugs containing insulin or antibiotics (see also note 115 below). Food and color additives, pesticides used on agricultural commodities, human and animal drugs, and medical devices are all subject to this approach. The only chemical substances covered by the Act which are not presumed to be unsafe are those which are used in cosmetics. If the FDA determines that any such chemical is "poisonous or deleterious" however, its use may be regulated or prohibited as an "adulterated" cosmetic.[14] In Helene Curtis Enterprises, Inc. v. Pruitt,[15] the Fifth Circuit Court of Appeals stated: "In order for cosmetics to be 'adulterated,' they must cause harm under conditions of use which are prescribed by the directions or must be used in the customary and usual fashion."

The Act discusses safety standards only in the most general terms. The approach is typified by the food additive provisions. For example, no food additive may be marketed in interstate commerce until a regulation approving its use has been issued.[16] The Secretary cannot approve such a regulation unless "a fair evaluation of the data . . . establish[es] . . . that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe".[17] Similarly broad safety standards apply to substances throughout the Act, except in the case of carcinogens. More restrictive clauses, inserted largely through the efforts of Representative James Delaney, mandate that food additives, color additives, and new animal drugs may not be approved as safe if they are carcinogenic.[18] Proponents of the clause reason that because the mechanisms which cause cancer are unknown, no safe tolerance can be set for carcinogens. Thus, the Secretary may not permit even small amounts of carcinogens to be present in foods or animal drugs.

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[14] 21 USC § 361.

[15] 385 F.2d 841, 848 n.1 (5th Cir. 1967), cert. denied, 391 U.S. 913 (1968).

[16] 21 USC § 348.

[17] Ibid.

[18] 21 USC § 348(c)(3)(A) (food additives); 21 USC § 376(b)(5)(B) (color additives); 21 USC § 360b(d)(1)(H) (new animal drugs). An exception to the Delaney clause permits the use of a carcinogenic food additive in animal feeds. Such an additive may be approved if it does not adversely affect the animal fed, and if no residue of the additive is found "in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal." 21 USC §348(c)(3)(A). This exception also applies to carcinogenic color additives used in animal feeds and carcinogenic new animal drugs. 21 USC §376(b)(5)(B); 360b(d)(1)(H).

Because of its wide coverage, the FDCA has been the subject of much litigation. Again and again, the courts have held that the Act is to be broadly construed.[19] These are the oft-cited words of the United States Supreme Court:

> The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates -- and equally clearly, broader than any strict medical definition might otherwise allow. . . . But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principal that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with 'efficacy' and 'safety.'[20]

This liberal construction has colored the judicial opinions in this area and is reflected in many of the decisions which are cited in this statutory review.

Although the FDCA has been interpreted broadly, it has not been interpreted to affect the administration of other statutes. In *Continental Chemiste Corporation v. Ruckelshaus*,[21] for instance, the Seventh Circuit Court of Appeals held that merely because the use of an economic poison in compliance with directions on the label caused certain food to become "adulterated" under the FDCA did not mean that the poison was "misbranded" under the Federal Insecticide, Fungicide, and Rodenticide Act.

Exhibit 3-3 contains a brief description of the safety determination and FDA action which must occur before a regulated product can be marketed.

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[19] *See*, *for example*, *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1969), *reh. denied*, 395 U.S. 954 (1969); *AMP Inc. v. Gardner*, 389 F.2d 825 (2nd Cir. 1968), *cert. denied*, 393 U.S. 825 (1968), *reh. denied*, 395 U.S. 917 (1969); *United States v. Naremco, Inc.*, 553 F.2d 1138 (8th Cir. 1977); *Meserey v. United States*, 447 *F.*Supp. 548 (D.C. Nev. 1977).

[20] *Bacto-Unidisk*, *supra*, 394 U.S. at 798.

[21] 461 F.2d 331 (7th Cir. 1972).

EXHIBIT 3-3

SUMMARY OF SAFETY DETERMINATION AND FDA ACTION

Pesticide Chemicals	• A tolerance for residues on raw agricultural commodities must be set "to the extent necessary to protect the public health." • The level of the tolerance is based on a broad cost/ benefit analysis which examines the economic, environmental, and health effects resulting from use of the pesticide chemical.
Food Additives	• A regulation must be issued "prescribing the conditions under which the additive may be safely used." • The regulation is based primarily on the safety risks of the additive. • Generally, the maximum permissible concentration of the additive must be 1% or less of the concentration which produces no effect in experimental animals.
Color Additives	• A regulation must be issued "prescribing the conditions under which the additive may be safely used." • The regulation is based primarily on the safety risks of the additive. • Generally, the maximum permissible concentration of the additive must be 1% or less of the concentration which produces no effect in experimental animals.
New Drug	• A new drug application may only be approved after the FDA determines that the drug is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling." • Approval as safe is based on a balancing of the therapeutic risks and benefits of the drug.

EXHIBIT 3-3

SUMMARY OF SAFETY DETERMINATION AND FDA ACTION
(Continued)

New Animal Drug	• A new animal drug application may only be approved after the FDA determines that the drug is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling." • Approval as safe is based on a balancing of the therapeutic risks and benefits of the drug.
Medical Devices	• For Class III devices, the FDA must approve the device after determining that it is safe and effective "under the conditions of use prescribed, recommended, or suggested in the proposed labeling." • Approval as safe is based on a balancing of the therapeutic risks and benefits of the drug.
Cosmetics	• No FDA approval is necessary before a cosmetic or cosmetic ingredient may be marketed. • If the FDA demonstrates that a cosmetic or ingredient is a "poisonous or deleterious" substance, then it is considered adulterated and barred from interstate commerce.

Mandatory Reporting Requirements

Before a manufacturer or processor can market a food containing an added chemical substance, or distribute a drug, animal drug, or medical device, he must petition the Secretary to approve the food additive, drug, animal drug, or device as safe.[22] The petition must carefully identify the substance for which approval is sought and fully report all information pertaining to the safety of the item.[23] Any study or investigation which indicates that the item may be unsafe must be included.[24]

Generally, once the Secretary has approved the use of an item, further information concerning possible dangers or safety violations does not have to be reported. There are, for example, no statutorily mandated reporting requirements for incidents concerning food or color additives or pesticide chemicals on raw agricultural products. Cosmetic manufacturers, who do not need to obtain premarket approval for their products or ingredients, are also not mandated to report safety violations or incidents. The Act does require the manufacturer of any approved drug, animal drug, or medical device to report any information he obtains which may indicate that the regulated item is unsafe. (See Exhibit 3-2.) Similarly, he must report any information concerning the safety of a drug, animal drug, or medical device which is exempt from the general approval process because it is being used solely for investigational purposes.

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[22] 21 USC §§ 348 (food additive), 355 (drug), 360b (animal drug), 360e (device). Efficacy issues are not included in this review.

[23] Ibid.

[24] Ibid.

PESTICIDE CHEMICAL ACT OF 1954

The Pesticide Chemical Act[25] was designed to modify and enlarge a provision of the 1938 FDCA which was underutilized by the government and food industries. The original FDCA allowed the Secretary to approve the use of a "poisonous or deleterious substance" in a food if the substance was required in production or could not be avoided by good manufacturing practice.[26] When granting an approval, the Secretary was to prescribe a maximum concentration for the substance in foods "to such extent as he finds necessary for the protection of public health."[27] Before he could set the concentration level, the Secretary had to hold formal public hearings and make detailed findings concerning safe residue levels in foods. Unfortunately, the process was lengthy and cumbersome. As a result, while most pesticide chemicals would have been considered poisonous or deleterious on foods, only one formal tolerance for a pesticide was set between 1938 and 1954. Instead, industries and the government followed unofficial tolerance levels.[28]

Recognizing pesticide chemicals as uniquely necessary "poisonous and deleterious substances", and wishing to afford greater protection to the public health by simplifying and speeding up procedures regulating such substances, Congress enacted the Pesticide Chemical Act of 1954.[29] While the older provision only allowed the government to regulate pesticides which had been identified as "poisonous or deleterious," the new section automatically covered all pesticides.[30] In addition, the bill prescribed specific time limits for regulatory review to assure that petitions for approval would be evaluated expeditiously.[31]

Authority for Regulation under the Act

In general, the FDCA is administered by the Secretary of Health and Human Services through the Commmissioner of the FDA. Since 1970, however, the Administrator of EPA has overseen the use of pesticides on raw agricultural commodities. Petitions for approval are submitted to the Administrator who must first certify that the pesticide is useful and then evaluate its safety and set a maximum tolerance for the substance.

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[25] July 22, 1954, ch. 559, 68 Stat. 511, codified as 21 USC § 346a.

[26] 21 USC § 346.

[27] Ibid.

[28] S. Rep. No. 1635, 83rd Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News, 2626-2628 (1954).

[29] Ibid.

[30] 21 USC § 346a.

[31] 21 USC § 346a(d).

A question arose in Environmental Defense Fund v. U.S. Department of HEW[32] whether the Secretary of HEW[33] had to wait until the Secretary of Agriculture deregistered DDT before HEW could establish zero tolerances for it. The court held that HEW did not have to wait, saying:

> While it is obvious that the responsibilities of the two Secretaries are interrelated and ought to be coordinated, we think their individual responsibilities are quite clear and quite separate. The Secretary of HEW is given the primary responsibility for determining the amount of residue of a pesticide which can safely -- from the viewpoint of the food consumer -- be left on raw agricultural commodities. It is true that in establishing a tolerance the Secretary of HEW must take into account the Agriculture Secretary's opinion regarding the agricultural usefulness of the pesticide, but that is only one of many factors which HEW must consider. In our judgment, the Act's language requires that HEW make its own independent judgment, based on public health considerations, as to the tolerance which should be set for pesticide residues on raw agricultural commodities and not abdicate its responsibility to the Department of Agriculture.[34]

Chemical Substances Covered

The amended FDCA covers any "pesticide chemical" that is "used in the production, storage, or transportation of raw agricultural commodities."[35] The term "pesticide chemical" means any substance which, alone or in combination with any other substances, is a pesticide as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[36] "Pesticide chemicals" in processed foods are not covered by this section. They are treated as "food additives" under Section 409 of FDCA.[37]

Statutory Criteria and Factors for Regulation

Any "pesticide chemical" used on a raw agricultural commodity "shall be deemed unsafe" unless:

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[32] 428 F.2d 1083 (D.C. Cir. 1970).

[33] Now, Health and Human Services. See note 2, supra.

[34] 428 F.2d at 1087.

[35] 21 USC § 321(q).

[36] Ibid. FIFRA is found at 7 USC § 136 et seq. See the statutory and regulatory reviews of that Act.

[37] 21 USC § 348.

1. The Administrator has set a tolerance for the chemical on that commodity,
2. The Administrator has exempted the chemical from a tolerance because "such a tolerance is not necessary to protect the public health," or
3. The pesticide is "generally recognized as safe" (GRAS).[38]

In setting a tolerance, the Secretary should limit the concentration of the "pesticide chemical" on the food "to the extent necessary to protect the public health."[39] The Administrator should at least consider:

1. the necessity of the chemical to the production of an "adequate, wholesome, and economical food supply,"
2. other ways in which the consumer may be affected by the same or similar substances (i.e., other exposures), and
3. the usefulness of the chemical.[40]

Pesticide chemicals in or on a raw agricultural commodity are not covered by a Delaney-type clause. The court in Environmental Defense Fund v. U.S. Department of HEW,[41] said, "[W]e do not think the Delaney anticancer amendment can be held to apply full force to pesticide chemicals." That court also quoted both the Senate and House Reports on the Pesticide Chemical Act:

> Before any pesticide-chemical residue may remain in or on a raw agricultural commodity, scientific data must be presented to show that the pesticide-chemical residue is safe from the standpoint of the food consumer. The burden is on the person proposing the tolerance or exemption to establish the safety of such pesticide-chemical residue.[42]

Thus, the court concluded that if a substance is found to be a carcinogen, the Secretary may permit tolerances for it greater than zero, but he would "be required to explain the basis on which he determined such tolerances to be 'safe.'"[43]

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[38] 21 USC § 346a.

[39] 21 USC § 346a(b).

[40] Ibid.

[41] 428 F.2d 1083, 1091 (D.C. Cir. 1970).

[42] Footnote omitted. 428 F.2d at 1092.

[43] Ibid.

Information Required for Approval

An applicant who wants the Administrator to approve the use of a pesticide chemical on an agricultural commodity must prove that the substance is safe for its intended use. He must submit a petition containing:

> (A) the name, chemical identity, and composition of the pesticide chemical;
>
> (B) the amount, frequency, and time of application of the pesticide chemical;
>
> (C) full reports of investigations made with respect to the safety of the pesticide chemical;
>
> (D) the results of tests on the amount of residue remaining [on commodities], including a description of the analytical methods used;
>
> (E) practicable methods of removing residue which exceeds any proposed tolerance;
>
> (F) proposed tolerances for the pesticide chemical if tolerances are proposed; and
>
> (G) reasonable grounds in support of the petition.[44]

The Distict of Columbia Court of Appeals, in Environmental Defense Fund v. U.S. Department of HEW,[45] commented as follows on these requirements:

> Both House and Senate reports emphasize that the formal requirements for a petition are to be flexibly administered in the interest of safeguarding the public health:
>
> > 'It is intended that a rule of reason should dictate the nature and extent of the information which should be submitted with a petition. What is contemplated is data adequate to permit an accurate appraisal of safety to protect the public health. In this respect the data as to a particular chemical will depend upon many variable factors, including its physical and chemical properties, recommended purpose, toxicity, and rate of disappearance. The emphasis to

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[44] 21 USC § 346a(d)(1).

[45] Footnote omitted. 428 F.2d 1083, 1089 (D.C. Cir. 1970).

> be placed on any such factor will similarly depend on the particular pesticide chemical under consideration and its proposed usage. * * *'

No Mandatory Reporting of Incidents

Once a pesticide chemical has been approved for use and tolerances have been set, the FDCA imposes no mandatory requirements to report incidents or contaminations concerning the substance.

FOOD ADDITIVES AMENDMENT OF 1958

Since 1938, the FDCA prohibited the use of unsafe substances in food. Prior to 1958, before the use of a dangerous chemical could be banned, however, the federal government had to prove it was "poisonous or deleterious." Once a suspicious chemical was identified, it often took two years or more to complete scientific testing to prove whether the substance was unsafe.[46] During that period, unscrupulous food processors could continue to use the additive with impunity.

To address the dangerous situation, Congress passed the Food Additive Amendment of 1958[47] which shifted the burden of proof to processors by requiring them to demonstrate that an additive was safe *before* it could be used. This action not only extended further protection to consumers, it also aided honest food processors. The great majority of processors--accounting for 95 percent of foodstuffs produced--conducted their own safety tests for food additives. Until the passage of this amendment, they were subject to unfair price competition from the processors who ignored safety considerations.

Chemical Substances Covered

The amendment broadly defines "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food."[48] Substances which are generally recognized as safe (GRAS) by scientific experts are a major exception; they are not considered food additives.[49] This GRAS provision was added to exempt substances from scientific safety testing if their safety had already been demonstrated by long term common use in food.[50] The term "food additive" also excludes "color additives," certain pesticide chemicals, and substances which have been previously approved under the FDCA, the Poultry Products Inspection Act, or the Meat Inspection Act.[51]

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[46] The information contained in this paragraph and the next is generally from S. Rep. No. 2422, 85th Cong., 2nd Sess., *reprinted in U.S. Code Cong. and Ad. News*, 5300-5302 (1958).

[47] Sept. 6, 1958, Pub. L. No. 85-929, 72 Stat. 1785, generally codified as 21 USC § 348.

[48] 21 USC § 321(s).

[49] *Ibid*.

[50] S. Rep. No. 2422, 85th Cong., 2nd Sess., *reprinted in U.S. Code Cong. and Ad. News*, 5300, 5303 (1958).

[51] 21 USC § 321(s).

Any radiation used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food is also considered a food additive.[12] Like other food additives, radiation may not be used without regulatory approval.

The legislative history sheds some light on the intended coverage of the food additives provisions. The Senate Report on the Food Additives Amendment of 1958 stated:

> The legislation covers substances which are intentionally added to food. These additives are generally referred to as 'intentional additives.'
>
> The legislation also covers substances which may reasonably be expected to become a component of any food or to affect the characteristics of any food. These substances are generally referred to as 'incidental additives.'
>
> The principal examples of both intentional and incidental additives are substances intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food.
>
> On the other hand, substances which may accidentally get into a food, as for example, paints or cleaning solutions used in food processing plants, are not covered by the legislation. These additives are generally referred to as 'accidental additives,' since these substances if properly used may not reasonably be expected to become a component of a food or otherwise to affect the characteristics of a food. If accidental additives do get into food, the provisions of the Food, Drug, and Cosmetic Act dealing with poisonous and deleterious substances would be applicable.[13]

Several courts have had occasion to rule on the scope of the substances covered by the term "food additive." In considering a product called Ferro-Lac, the Fifth Circuit Court of Appeals held:

> It does not matter under the Act if Ferro-Lac is in fact safe or whether the residues would be different if the individual ingredients were tested. The sole criterion for identifying a food additive is whether a substance which may become a component of or affect the characteristeics of any food be not generally recognized among qualified experts as having been shown to be safe, 21 USC § 321(s).[14]

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[12] Ibid.

[13] S. Rep. No. 2422, 85th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News, 5300, 5303-5304 (1958).

[14] Emphasis added. United States v. 41 Cases, More or Less, Etc., 420 F.2d 1126, 1131 (5th Cir. 1970).

In Natick Paperboard Corp. v. Weinberger,[55] the court held that food-packaging materials may be found to be food additives. The court stated:

> The broadly protective intent of this legislation appears from the legislative history thereof. The Senate Committee report contains the statement, 'We want the record to show that in our opinion the bill is aimed at preventing the addition to the food our people eat of any substances the ingestion of which reasonable people would expect to produce not just cancer but any disease or disability.' Sen. Rpt. No. 2422, 85th Cong., 2d Sess. (1958), 3 U.S. Code Cong. and Admin. News, p. 5310 (1958). The legislative history further establishes that the House subcommittee analyzing the bill considered, and explicitly rejected on the ground of surplusage, a proposed amendment that would have brought 'food additive' within the definition of 'food.' The subcommittee spokesman, Rep. John Bell Williams, stated:
>
> > 'It was the feeling of the Committee that such a provision would be surplusage since the Present Food and Drug law, in section 201(f) [21 U.S.C.A. § 321(f)] already defines "food" as including all components thereof. Since substances which get into food incidentally in its manufacture, handling or packaging would be dealt with as a "food additive" under the bill, there appears to be no need to have such substances also defined as a "food."'[56]

A later case, Monsanto Company v. Kennedy,[57] set some limits on what food packaging may be found to be food additives. The District of Columbia Court of Appeals held that the FDA may not find that food-packaging materials become a component of the food contained in it merely on the basis of the diffusion principle, which states that "any two substances that are in contact will tend to diffuse into each other at a rate that will be determined as a function of time, temperature, and the nature of the substances".[58] The court found that "Congress did not intend that the component requirement of a 'food additive' would be satisfied by a mere recitation of the diffusion principle, a mere finding of any contact whatever with food."[59]

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[55] 389 F. Supp. 794 (D.C. Mass. 1975), affirmed, 525 F.2d 1103 (1st Cir. 1975), cert. denied, 429 U.S. 819 (1976).

[56] Some citations omitted. 389 F. Supp. at 797.

[57] 613 F.2d 947 (D.C. Cir. 1979).

[58] Emphasis in original. 613 F.2d at 955.

[59] Ibid.

Other cases have interpreted the coverage of the food additives provisions rather broadly. For example, in *United States v. Ewig Bros. Co., Inc.*,[60] the Court held that DDT and dieldrin found in smoked fish were food additives despite the fact that these substances were in the raw fish even before the smoking process began. In *National Nutritional Food Association v. Kennedy*,[61] the court upheld a regulation which allowed vitamins and minerals in dietary supplements which are not generally recognized as safe to be treated as food additives. In so ruling, the Court also held that a substance may qualify as a food additive even if it also qualifies as a food under the FDCA.

Statutory Criteria and Factors for Regulation

Following the preventive principles of the FDCA, *any* food additive is considered unsafe unless the Secretary (1) has approved a regulation governing the conditions under which the additive *"may be safely used"* or (2) has granted an exemption for investigational use by qualified experts.[62] The court in *United States v. Articles of Food . . . Buffalo Jerky*[63] interpreted the effect of this section as follows: "The language of the statute establishes a presumption that the food additives are unsafe unless one of the exceptions is established."

When evaluating the safety of a "food additive," the statute directs the Secretary to consider at least:

> (A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;
>
> (B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and
>
> (C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.[64]

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[60] 502 F.2d 715 (7th Cir. 1974), *cert. denied*, 420 U.S. 945 (1975).

[61] 572 F.2d 377 (2nd Cir. 1978).

[62] 21 USC § 348.

[63] 456 F. Supp. 207, 210 (D.C. Nebr. 1978).

[64] 21 USC § 348(c)(5).

The concept of safety was of significant importance to the legislators in passing the Food Additives Amendment of 1958. The legislative history had this to say:

> The concept of safety used in this legislation involves the question of whether a substance is hazardous to the health of man or animal. Safety requires proof of a resonable certainty that no harm will result from the proposed use of an additive. It does not -- and cannot -- require proof beyond any possible doubt that no harm will result under any conceivable circumstance.
>
> This was emphasized particularly by a scientific panel which testified before the subcommittee. The scientists pointed out that it is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of any chemical substance.
>
> In determining the 'safety' of an additive, scientists must take into consideration the cumulative effect of such additive in the diet of man or animals over their respective life spans together with any chemically or pharmacologically related subtances in such diet. Thus, the safety of a given additive involves informed judgments based on educated estimates by scientists and experts of the anticipated ingestion of an additive by man and animals under likely patterns of use.
>
> Reasonable certainty determined in this fashion that an additive will be safe, will protect the public health from harm and will permit sound progress in food technology.[45]

The manufacturer or processor who has applied for approval must prove with reasonable certainty that the additive will be safe for its intended use. If necessary, the Secretary may approve a substance but set conditions on its use.[46] He may, for example, restrict an additive to certain foods or set maximum tolerance levels (i.e., not to exceed 75 ppm in salad dressing). The Secretary may not identify a "food additive" as safe for use "if it is found...to induce cancer in man or animal."[47]

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[45] S. Rep. No. 2422, 85th Cong., 2nd Sess., *reprinted in U.S. Code Cong. and Ad. News*, 5300, 5305 (1958).

[46] 21 USC § 348(d).

[47] 21 USC § 348(c)(3)(A). See note 18 *supra*, for the exceptions to the Delaney Clause.

Information Required for Approval

When submitting an application for approval of a food additive, the applicant's petition must include:

> (A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;
>
> (B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;
>
> (C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quanitty of such additive required to produce such effect;
>
> (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and
>
> (E) full reports of investigations made wih respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.[**]

No Mandatory Reporting Requirements

Once a food additive has been approved for use, there are no statutory requirements to report incidents or contaminations concerning it.

[**] 21 USC § 348(b)(2).

COLOR ADDITIVE AMENDMENTS OF 1960

Prior to the passage of the Color Additive Amendments of 1960,[69] the Commissioner of the FDA had certified 118 color additives for use in foods, drugs, or cosmetics.[70] Only 19 of those colors, however, were approved for use in foods, drugs, and cosmetics. As scientific testing methods improved, the FDA began to receive information which indicated that many approved colors were toxic under certain extreme conditions. The original FDCA prohibited the certification of any unsafe color; and the safe-for-intended-use approach, adopted for food additives in 1958, did not cover color additives. As a result, the Commissioner had to de-certify seven of the 19 colors with unrestricted approval. More de-certifications were expected and industries began to fear that it would be impossible to find the approved colors they needed for foods, drugs, and cosmetics. Political pressure began to build for action similar to the food additives amendment which would allow the Secretary to approve a color additive if it was safe for use in a specified manner and within set tolerances. These pressures were supported by a 1956 National Academy of Sciences study which had recommended such an approach for the regulation of color additives.

A further stimulus for the bill was the specific plight of the citrus industry.[71] By 1955, investigations revealed that Red Dye #32, the color used by growers to dye naturally greenish mature oranges, was toxic under some conditions. Though it was safe for coloring oranges, the FDA was statutorily forced to decertify the color because it was not safe under all conditions.

Through special legislation, Congress allowed growers to continue using the dye temporarily. In 1959, further legislation substituted the newly developed Red Dye #2 for #32. The new color was itself toxic under some conditions, but posed a lesser threat than #32. The legislation specified that Red Dye #2 could only be used until August 1961, unless Congress took further action.

In 1960, the Color Additives Amendment resolved the problem. It moved away from the absolute requirement of safety and permitted the Secretary to certify a color for use if it were safe under conditions which he prescribed. The amendment further required that each "batch" of a dye be certified by the Secretary as safe for use.

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[69] July 12, 1960, Pub. L. No. 86-618, 74 Stat. 399, generally codified as 21 USC § 376.

[70] This paragraph is generally from H.R. Rep. No. 1761, 86th Cong., 2nd Sess., reprinted in U.S. Code and Cong. Ad. News, 2887-2891 (1960).

[71] The following three paragraphs were developed generally from S. Rep. No. 795, 86th Cong., 1st Sess. (1959) and H.R. Rep. No. 1761, 86th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 2887 (1960).

Chemical Substances Covered

While the original FDCA covered only coal-tar based colors, the amended Act regulates all color additives. The statute exempts materials which impart color but are used solely for other purposes:

> The term 'color additive' means a material which--
>
> (A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and
>
> (B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or thrugh reaction with other substance) of imparting color thereto;
>
> except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.[72]

For example, pesticides and nutrients which color as a side effect are not covered by this section; they are regulated in separate provisions of the Act.

Statutory Criteria and Factors for Regulation

Any color additive is considered unsafe unless (1) it is approved for the particular use by the Secretary and comes from a certified "batch" of dye or batch that has been exempted from certification requirements, or (2) it has been granted an exemption for investigational use by experts.[73] Because of the small number of colors used in foods, drugs, and cosmetics, there is no need to exempt some colors from the approval process by creating a generally recognized as safe (GRAS) category similar to that used in the food additives provisions. In evaluating the safety of a "color additive" the Secretary must consider at least the following:

> (i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs or devices, or cosmetics because of the use of the additive;

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[72] 21 USC § 321(t)(1). In 21 USC § 321(t)(3), an exception from this definition is made for certain agricultural chemicals that affect color only as a by-product of their main function.

[73] 21 USC §376.

> (ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;
>
> (iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and
>
> (iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug or device, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.[74]

It should be noted that the harmfulness of a color additaive is based on "the toxicity of the color itself, rather than of the food, drug or cosmetic in which it may be used."[75] In addition, the Secretary may not identify a "color additive" as safe or set conditions for its use "if it is found to induce cancer in man or animal."[76]

Information Required for Approval

Unlike provisions relating to other chemicals which require approval from the Secretary, the color additive sections do not specify the information an applicant must supply in a petition for approval. However, the general administrative provisions of the act empower the Secretary to pass regulations as necessary "for the efficient enforcement of" the FDCA.[77] Through such regulations, the Secretary requires that an applicant submit the same comprehensive identity and safety information concerning color additives as is required for food additive. See the regulatory review of the FDCA for additional information.

No Mandatory Reporting Requirements

Once a color additive has been approved for use, there are no statutory requirements to report incidents or contaminations concerning the substance.

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[74] 21 USC § 376(b)(5)(A).

[75] Certified Color Industry Committee v. Secretary of HEW, 283 F.2d 622, 624 (2nd Cir. 1960).

[76] 21 USC § 376(b)(5)(B). See note 18, supra, for exceptions to the Delaney Clause.

[77] 21 USC § 371.

COSMETICS

Cosmetics were not covered by the 1906 Pure Food and Drug Act. As pressure to expand the scope of that law arose in the 1930s, however, legislators recognized that federal law did not protect consumers from adulterated or misbranded cosmetics. Indeed, in the years just prior to the enactment of the FDCA, consumers were flooded with deceptive advertising claims concerning cosmetics. This led to the inclusion of cosmetics in the Act's coverage in 1938.[78]

Chemical Substances Covered

Cosmetics are defined under FDCA as:

> (1) articles intended to be rubbed, poured, sprinked, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.[79]

Unlike most other products covered by the FDCA, cosmetics do not require premarketing approval before they can be sold in interstate commerce. Instead, if the government determines that a cosmetic contains a "poisonous or deleterious substance," the product will be deemed adulterated and prohibited from interstate commerce.[80] Thus, the government may regulate toxic substances in cosmetics, but it bears the burden of proving that a cosmetic or an ingredient is unsafe. This may not be an extremely heavy burden, however, since, in a personal injury case, one court has ruled that nail polish base coat may reasonably be found to contain a "deleterious substance" if the polish causes "much allergic reaction . . . particularly so where the labeling does not warn of the possible reaction and indicate proper precautions."[81]

The FDCA specifically excludes coal-tar hair dyes which are properly labeled from classification as poisonous or deleterious.[82] There is also no Delaney-type clause prohibiting the presence of any carcinogen in a cosmetic.

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[78] 21 USC §§ 361-363. See generally, H.R. Rep. No. 2139, 75th Cong., 3rd Sess. (1938).

[79] 21 USC § 321(i).

[80] 21 USC § 361, § 331.

[81] Gober v. Revlon, Inc., 317 F.2d 47, 52 (4th Cir. 1963).

[82] 21 USC § 361(a).

Information Required for Approval

Because cosmetics and their ingredients do not require premarketing approval from the FDA, manufacturers are not required to submit any information before introducing their product into interstate commerce.

No Mandatory Reporting Requirements

Manufacturers are not required to report any incident or contamination concerning toxics in cosmetics.

DRUG AMENDMENTS OF 1962

For several years before the passage of the Drug Amendment of 1962,[13] legislators had been concerned about inadequancies in the laws affecting drug safety. Drug reform legislation was pending before the 87th Congress when medical researchers traced thousands of birth defects in European infants to the use of the drug thalidomide by pregnant women. That discovery helped spur Congressional efforts to pass the pending legislation.

The legislation addressed several weak points in the original FDCA. Previously, drug manufacturers were required to adequately test the safety of their drugs before they were marketed. However, unless the FDA could conclude that a drug was unsafe six months after a drug application was submitted, the application was automatically approved. Another weak point required manufacturers to show their drug was effective only if it was used to treat life-threatening diseases or if it appeared to produce serious toxic effects. Finally, once a new drug was approved, manufacturers were not required to report new information concerning adverse patient reaction to the drug.

The Drug Amendments of 1962 addressed these problems by requiring manufacturers to prove both the safety and efficacy of all new drugs, extending the FDA's application review period, and creating mandatory reporting requirements.

Chemical Substances Covered

FDCA defines "drug" as

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories.[14]

Any drug introduced into interstate commerce is subject to the provision of the amendments as a new drug unless it is:

a. generally recognized as safe and effective by experts, or

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[13] Oct. 10, 1962, Pub. L. No. 87-781, 76 Stat. 781-783, 784, 785, 796, generally codified as 21 USC § 355.

[14] 21 USC § 321(g)(1).

b. a pre-1938 drug which was subject to the Pure Food and Drug Act and whose label representations concerning conditions of use have not changed.[85]

Note that unlike previous amendments discussed, "generally recognized" here includes both safety and effectiveness. However, through these two exceptions, drugs which have stood the test of time need not be subjected to the application procedures for truly new or less-accepted drugs.

The courts have interpreted the statutory definition of "drug" very broadly:

> Furthermore, the legislative history, read in light of the statute's remedial purpose, directs us to read the classification 'drug' broadly, and to confine the device exception as nearly as is possible to the types of items Congress suggested in the debates. . . United States v. An Article of Drug . . . Bacto-Unidisk.[86]
>
> Since the only significance in classifying AMP's products as either 'drugs' or 'devices' is that if they are 'drugs' they may be subject to the 'new drug' provisions of the Act, we must classify them with reference to the purpose for which Congress enacted those provisions. That purpose was, very clearly, to keep inadequately tested medical and related products which might cause widespread danger to human life out of interstate commerce. The product which immediately precipitated Congressional concern -- 'Elixir Sulfanilamide' -- was a drug within the everyday, narrow sense of the word, but we would hardly suppose that when Congress incorporated the 'new drug' bills resulting from the 'Elixir Sulfanilamide' tragedy into an Act which contained an extremely broad definition of the word 'drug' it intended that the operation of those provisions should be restricted to products commonly called 'drugs,' and that products such as ligatures, which might present the very dangers the provisions were designed to meet, should be excluded. We would, moreover, be reluctant to give a narrow construction to this statute, touching the public health as it does. AMP, Inc. v. Gardner.[87]

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[85] 21 USC § 321(p).

[86] Footnote omitted. 394 U.S. 784, 799-800 (1969), reh. denied, 395 U.S. 954 (1969).

[87] 389 F.2d 825, 829-830 (2nd Cir. 1968), cert. denied, 393 U.S. 825 (1968), reh. denied, 395 U.S. 917 (1969).

> From the preceding discussion, it is clear that whenever there is a problem of construction, the duty of the courts is to liberally construe provisions of the Act, being mindful of its overriding purpose to protect the public health. *Meserev v. United States*.[88]

In this last case, the court went on to say: "Under the Act, the safety of an article is not the determining factor. Instead, the determination under the Act is based upon the article's listing in the Pharmacopoeia or its intended use."[89] In short, it matters not how dangerous something is, but only whether it falls within the statutory definition of a 'drug,' as this term is broadly construed.[90]

It has repeatedly been held that the intended use of an article determines whether it is a 'drug' for purposes of the FDCA. As stated in *Hanson v. United States*:[91]

> Thus, it is the *intended* use of an article which determines whether or not it is a 'drug,' and even the most commonly ingested foods and liquids are 'drugs' within the meaning of the Act if their intended use falls within the definition of §321(g)(1)(B).

This case and several others[92] have, under this rule, held laetrile to be a drug subject to the FDCA. Not even the use of that drug by terminally ill patients is exempted.[93] The reach of the definition is so far that it includes honey, when it is claimed to be a panacea,[94] and peppermint tea leaves, when intended to be used as drugs.[55] It does not even matter what the actual effect of the product is: "Regardless of the actual physical effect of the product, once it is established that its intended use brings it within the drug definition, it will be deemed a drug for purposes of the Act."[56]

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[88] 447 F. Supp. 548, 553 (D.C. Nev. 1977).

[89] 447 F. Supp. at 553.

[90] This broad construction is not to be taken too far, however: "Here again, in our construction of this explicit Act, we must be sensitive to what Congress has written, and recall that 'It is for us to ascertain -- neither to add nor to subtract, neither to delete nor to distort.'" *Fleming v. Florida Citrus Exchange*, 358 U.S. 153, 166 (1958), *reh. denied*, 358 U.S. 948 (1959).

[91] Citations omitted. 417 F. Supp. 30, 34 (D.C. Minn. 1967), *affirmed*, 540 F.2d 947 (8th Cir. 1976). See also the cases cited there; *Gadler v. U.S.*, 425 F. Supp. 244 (D. Minn. 1977) and cases cited there at 246-247; *National Nutritional Foods Association v. Mathews*, 557 F.2d 325 (2nd Cir. 1977) and cases cited there at 333-334.

[92] *Hanson v. United States*, *supra*; *United States v. Articles of Food and Drug*, 444 F. Supp. 266 (D.C. E.D. Wisc. 1978).

[93] *United States v. Rutherford*, 442 U.S. 544 (1979).

[94] *United States v. 250 Jars . . . U.S. Fancy Pure Honey*, 218 F. Supp. 208 (E.D. Mich. 1963), *affirmed*, 344 F.2d 288 (6th Cir. 1965).

The courts have also addressed, on numerous occasions, the question of how this "intended use" is to be determined. The court in United States v. Articles of Drug, Etc.[57] stated: "Courts have uniformly held that the search for the 'intended use' of a product is not limited to the label on the container and may extend to oral and written representations about the products." An interesting rationale for this rule was given in United States v. Nutrition Service, Inc.:[58]

> The real test is how was this product being sold? If as a food, was it for the furnishing of energy and body building? Or was it being sold for the treatment and mitigation of disease? The answer is presented all through the evidence that treatment, cure, mitigation and prevention of disease was the purpose for which Mucorhicin was sold by the defendants and bought (and very frequently prescribed) by the purchasers. No matter how loud and long one may declaim that black is white, black is nevertheless black.

The representations that may be used to determine the intended use of an article include "its label, accompanying labeling, promotional material, advertising, and any other relevant source."[59]

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[55] United States v. Hohensee, 243 F.2d 367 (3rd Cir. 1957), cert. denied, 353 U.S. 976 (1957), reh. denied, 354 U.S. 927 (1957).

[56] Meserey v. United States, 447 F. Supp. 548, 553 (D.C. Nev. 1977).

[57] 263 F. Supp. 212 (D.C. Nebr. 1967).

[58] 227 F. Supp. 375, 386 (D.C. W.D. Penn. 1964), affirmed, 347 F.2d 233 (3rd Cir. 1965).

[59] United States v. Article . . . Consisting of 216 Cartoned Bottles . . . "Sudden Change," 409 F.2d 734, 739 (2nd Cir. 1969) and cases cited therein.

An interesting line of cases concerning creams promising to smooth wrinkled skin deals with the issue of determining the status of such creams under the FDCA. The first of these to be discussed here, United States v. Article Consisting of 36 Boxes, . . . "Line Away Temporary Wrinkle Smoother, Coty,"[100] found that "Line Away Temporary Wrinkle Smoother" was a drug, stating "a Court should be reluctant to give the Act a narrow construction, touching as it does the lives and health of people who are largely beyond self-protection."[101] In 1969, the next year, a similar product, "Sudden Change," was also found to be a drug, so long as it is claimed to give a "face lift without surgery" and to "lift out puffs."[102] The central issue there was whether these claims were mere puffery which virtually everyone would accept as such and discount appropriately. The court held that:

> In other words, with the exception of those claims which have become so associated with the familiar exaggerations of cosmetics advertising that virtually everyone can be presumed to be capable of discounting them as puffery, the question of whether a product is 'intended to affect the structure * * * of the body of man * * *' is to be answered by considering, first, how the claim might be understood by the 'ignorant, unthinking or credulous' consumer, and second, whether the claim as so understood may fairly be said to constitute a representation that the product will affect the structure of the body in some medical -- or drug-type fashion, i.e., in some way other than merely 'altering the appearance.'[103]

The test enunciated in Sudden Change was utilized two years later in a case dealing with "Magic Secret."[104] The opposite conclusion was reached there, however, because the claims for "Magic Secret" were less exaggerated than in the prior two cases just discussed.

Just because a substance is a drug does not mean that it may not be distributed in interstate commerce. There are two major exceptions, as indicated at the beginning of this section. The exception which is of greater interest here is the one requiring that the drug be generally recognized as safe and effective.

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[100] 284 F. Supp. 107 (D.C. Dela. 1968), affirmed, 415 F.2d 369 (10th Cir. 1969).

[101] 284 F. Supp. at 111.

[102] United States v. Article . . . Consisting of 216 Cartoned Bottles . . . "Sudden Change," 409 F.2d 734 (2nd Cir. 1969).

[103] Footnotes omitted. 409 F.2d at 741-742.

[104] United States v. Article of Drug . . . 47 Shipping Cartons . . . "Helene Curtis Magic Secret . . .," 331 F.Supp. 912 (D.C. Md. 1971).

As pointed out in United States v. Article of Drug . . . "Mykocert":[105]

> The words 'generally recognized' as they appear in 21 U.S.C. § 321(p) are terms of art and their interpretation as in the context of drug usage poses various problems that have led to the case law development of certain objective indications of recognition and non-recognition.

The court in that case went on to discuss these indications:

> One indication that a drug is not generally recognized among qualified experts as safe and effective for its intended use, that some Courts have accepted, is the absence of any published medical or scientific literature relating to the usage of the drug since the lack of documented sources of information perforce curtails the widespread knowledge of the drug's effectiveness or safety. This test by itself has been recognized as determinative of 'newness' by several cases especially in this district.[106]
>
> Other Courts have searched for proof of general recognition in different, other directions and have required a higher degree of proof to establish non-recognition.
>
> * * *
>
> Some difficulty has been encountered by the Courts in determining precisely what degree of recognition both in quantity and quality constitutes 'general recognition' under the statute and that task is rendered all the more difficult when it must be accomplished within the strict confines of the summary judgment rule on the basis of conflicting affidavits which all claim expertise in the field. Some cases have taken the position that the mere existence of conflict between qualified experts in supporting affidavits establishes a lack of general recognition as a matter of law while other Courts in dicta attempted to soften the mere conflict rule where a genuine difference of opinion exists since general recognition ought not mean unanimous recognition.

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[105] 345 F. Supp. 571, 574 (D.C. N.D. Ill. 1972).

[106] In United States v. Article of Drug . . . "Bentex Ulcerine", 469 F.2d 875 (5th Cir. 1972), cert. denied, 412 U.S. 938 (1973), the court considered "almost non-existent" literature relating to the product persuasive but not conclusive evidence of non-recognition, although it ultimately held that the drug was not generally recognized as safe and effective.

> In addition to the various rules that have evolved in regard to the weight given affidavits in such an action certain guidelines developed pertaining to the qualifications of the affiants and the content of the affidavits. Some Courts have pointed out that the personal opinions of experts are not adequate to establish general recognition and that the affidavits should instead attest to the existence of the opinion or recognition in the general community. Furthermore, the affiant expert must be one qualified by scientific training and experience to evaluate the safety and effectiveness of drugs and cannot simply be a medical practitioner whose only knowledge is based on prescribing the drug for his own patients.[107]

Whatever test is used,

> [T]he hurdle of 'general recognition' of effectiveness requires at least 'substantial evidence' of effectiveness . . . In the absence of any evidence of adequate and well controlled investigations supporting the efficacy of [the product], a fortiori [it] would be a 'new drug' subject to the provisions of the Act.[108]

As stated in U.S. v. Articles of Drug Labeled Colchicine,[109] "The critical test is not whether the product is in fact safe, but whether there is general recognition among qualified experts as to that fact." Thus, only by fulfilling the tests mandated by the statute and the courts can a product be found to be generally recognized as safe and effective. As indicated in a law review article dealing with the FDCA,[110] this could lead to an anomalous result: "[A] safe drug not generally so recognized would be a new drug, and conversely, an unsafe drug generally recognized as safe would be an old drug."

Drugs can be deemed to be new drugs under the FDCA not only because they are actually new and do not fit under the two enumerated exceptions, but because they are being put to a new use or are part of a new combination of drugs (even though the component parts are all tried and tested). For example, a drug which is generally recognized as safe and effective in single dosage form has been held to be a new drug in time release capsules.[111] Similarly, in United States v. Article of Drug . . . "Mykocert,"[112] a drug which was a combination of a tampon and aminoacridines, both of which were generally recognized as safe and effective, was held to be a new drug.

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[107] Citations omitted. 345 F. Supp. at 574-575.

[108] Footnote omitted. Weinberger v. Hynson, Wescott & Dunning, 412 U.S. 609, 629-630 (1973).

[109] Emphasis added. 442 F. Supp. 1236, 1242 (D.C. S.D.N.Y. 1978).

[110] "Drug Efficacy and the 1967 Drug Amendments," 60 Georgetown L.J. 185, 187 (1971).

As can be easily seen, the provisions of the FDCA relating to drugs have engendered a good deal of litigation. It may well be asked what purpose all this litigation serves. As stated in National Nutritional Foods Association v. Mathews:[113] "The determination that an article is properly regulated as a drug, however, is not left to the Commissioner's unbridled discretion to act to protect the public health but must be in accordance with the statutory definition." The court system acts as a check on the FDA in carrying out its vital role in protecting the public. Perhaps this role is best summarized by this quote from Hanson v. United States,[114]

> The history of the Food, Drug, and Cosmetic Act in the courts demonstrates that there is no shortage of peddlers who claim that their miracle drug must be made available to the consuming public without further delay. A parallel history of product liability litigation also demonstrates the danger that new drugs may be released without adequate testing, too often with tragic consequences. The balance between these competing considerations is one which has already been struck by Congress, and it is one which has been repeatedly upheld by the courts. Only recently the Supreme Court reaffirmed this judgment in Weinberger v. Hynson, Wescott & Dunning, 412 U.S. 609, 622, 93 S.Ct. 2469, 2479, 37 L.Ed.2d 207 (1973):
>
> '. . . Congress surely has great leeway in setting standards for releasing on the public, drugs which may well be miracles or, on the other hand, merely easy money-making schemes through use of fraudulent articles labeled in mysterious scientific dress. The standards of "well-controlled investigations" particularized by the regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness. . . .'

---

[111] U.S. v. Articles of Drug Labeled Colchicine, 442 F. Supp. 1236 (D.C. S.D.N.Y. 1978). See also Hoffman v. Sterling Drug, Inc., 485 F.2d 132 (3rd Cir. 1973) and citations there at 137.

[112] 345 F. Supp. 571 (D.C. N.D. Ill. 1972).

[113] 557 F.2d 325, 334-335 (2nd Cir. 1977). See also Weinberger v. Hynson, Wescott & Dunning, 412 U.S. 609 (1973).

[114] 417 F. Supp. 30, 37-38 (D.C. Minn. 1976).

Statutory Criteria

No new drug may be introduced or delivered for introduction to interstate commerce unless the Secretary has approved the use of the drug.[115] The Secretary will not approve a new drug application (NDA) unless he finds that the manufacturer's application demonstrates that the drug is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling."[116] Approval will also be refused unless the Secretary finds, among other requirements, that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug are [adequate] to preserve its identity, strength, quality, and purity."[117]

The statute sets out the evidentiary showing which must be fulfilled for the Secretary to be able to determine that a new drug is sufficiently effective. The requirement is "substantial evidence that the drug will have the effect it purports or is represented to have,"[118] where "substantial evidence" is defined as:

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[115] 21 USC § 355(a). The Secretary approves new drugs through the new drug application (NDA) process (21 CFR 314) while exemptions from 21 USC § 355(a) (prohibiting unapproved new drugs from interstate commerce) for investigational purposes are obtained by wa of an investigational new drug (IND) notice (21 CFR 312). It should also be noted that any drug containing insulin or antibiotics is misbranded and hence may not be introduced into interstate commerce unless the Secretary has certified or issued a release for the batch from which the drug comes and such certificate or release is still in effect (although the Secretary may exempt certain drugs containing antibiotics from this rule). 21 USC 331(a), 35.2(k), 352(l), 356, 357. For simplicity, the discussion in the main text is limited to new drugs and does not specifically deal with drugs containing insulin or antibiotics.

[116] 21 USC § 355(d). To gain approval for drugs regulated under the original 1938 FDCA, manufacturers only had to demonstrate that their new drug was safe. The 1962 amendments provided that drugs previously approved under the 1938 Act would retain their approval even though they had not been demonstrated as effective. (21 USC § 201p, note.) Such drugs were subject to the other provisions of the amendments, however, and could have their approval revoked if the FDA finds that there is a "lack of substantial evidence" that the drug is effective. 21 USC 355(e). Pre-1962 drugs which were marketed without an approval because they were generally recognized as safe were also exempted from the requirements of demonstrated effectiveness. However, if new evidence suggests that they are either unsafe or ineffective, the FDA may classify them as new drugs subject to all of the requirements of other new drugs.

[117] 21 USC § 355(d).

[118] Ibid.

> evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.[119]

The United States Supreme Court has held that "the reach of scientific inquiry" is the same under this section as it is under the "generally recognized as safe and effective" requirement discussed above.[120]

Drugs being tested for safety and effectiveness may be exempted by regulation from the general provisions of this amendment.[121]

Information Required for Approval

A new drug application must contain:

> (1) full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;
>
> (2) a full list of the articles used as components of such drug;
>
> (3) a full statement of the composition of such drug;
>
> (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
>
> (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and
>
> (6) specimens of the labeling proposed to be used for such drug.[122]

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[119] Ibid.

[120] Weinberger v. Bentex Pharmaceuticals, Inc., 412 U.S. 645, 653 (1973).

[121] 21 USC § 355(i).

[122] 21 USC § 355(b).

Mandatory Reporting Requirements

Section 505(j)[123] of the FDCA authorizes the Secretary to require holders of an approved drug application to "establish and maintain such records, and make such reports to the Secretary" of information he may need "to determine, or facilitate a determination, whether there is or may be ground" for withdrawing approval for the drug because it may be unsafe or ineffective. Similarly, Section 505(i)[124] permits the Secretary to require safety and effectiveness reporting for drugs under investigation by experts.

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[123] 21 USC § 355(j).

[124] 21 USC § 355(i).

ANIMAL DRUG AMENDMENTS OF 1968

The FDCA was primarily designed to regulate products intended for human use. As a result, provisions concerning animal drugs were scattered throughout the Act and poorly coordinated. A "new animal drug," for instance, could be regulated under sections concerning "new drugs," "antibiotics," or "food additives." It was often more complicated to get a "new animal drug" approved than to gain approval for a new human drug. In response, Congress passed the 1968 amendments to consolidate the provisions concerning animal drugs.[125] Eliminating delays in the approval of safe and effective animal drugs benefits both producers and consumers.

Chemical Substances Covered

With a few exceptions, any animal drug introduced into interstate commerce is subject to the provisions of the Animal Drug Amendments as a new animal drug unless it is:

a. generally recognized as safe and effective, or

b. a pre-1938 drug which was subject to the Pure Food and Drug Act and whose label representations concerning conditions of use have not changed.[126]

Any animal drug previously approved as a "drug," "antibiotic," or "food additive" retains its approval as safe but it is subject to the general provisions of the Amendments. Any animal drugs marketed without approval before 1968 because they were generally recognized as safe are exempt from the new effectiveness requirements as long as their labeling does not change.

Several cases dealing with animal drugs have held that similar standards apply to these drugs as apply to non-animal drugs. For example, the court in United States v. Article of Drug . . . "Entrol-C Medicated"[127] ruled that the same standard of general recognition of safety and effectiveness applicable to non-animal drugs applies to animal drugs and that general recognition for the component parts of a drug supports a contention that the drug is not a new drug only if the combination is not itself greater or newer than its parts (note the similarity to the discussion of non-animal drugs at notes 112 to 113, supra). In addition, the court in United States v. Articles of Food and Drug Consisting of Coli-Trol 80, F4C-60 Feed Grade, Entrol-S Medicated, Entrol-P[128] relied on cases dealing with non-animal drugs in establishing the level of proof necessary to demonstrate general recognition of safety and effectiveness.

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[125] July 13, 1968, Pub. L. No. 90-399, 82 Stat. 343, 351, generally codified as 21 USC § 360b.

[126] 21 USC § 321(w).

[127] 513 F.2d 1127 (9th Cir. 1975).

[128] 518 F.2d 743 (5th Cir. 1975).

Statutory Criteria and Factors for Regulation

Any new animal drug covered by the FDCA is unsafe for distributioon in interstate commerce unless the Secretary has by regulation approved the use of the drug.[129] The Secretary must find that the manufacturer's application demonstrates that the drug is safe and effective for use "under the conditions prescribed, recommended, or suggested in the proposed labeling."[130] The Secretary must also find, among other requirements, that "the methods used in, and the facilities and controls used for, the manufacture, processing, and packaging of such drug are [adequate] to preserve its identity, strength, quality, and purity."[131]

When reviewing a new animal drug application "the Secretary shall consider, among other relevant factors":

> (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug,
>
> (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance,
>
> (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and
>
> (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice.[132]

Drugs being tested for safety and effectiveness by experts may be exempted by regulation from the general requirements of these provisions.[133]

In general, the Secretary may not approve the use of a "new animal drug" if it "induces cancer when ingested by man or animal."[134] However, "if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found . . . in any edible portions of such animals after slaughter or in any food yielded by or derived from the living animals," then the Secretary may approve the use of a carcinogenic animal drug.[135]

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[129] 21 USC § 360b(a).

[130] 21 USC § 360b(d).

[131] *Ibid*.

[132] 21 USC § 360b(d)(2).

[133] 21 USC § 360b(j).

[143] 21 USC § 360b(d)(1)(H).

Information Required for Approval

The petition for approval of a new animal drug shall contain:

> (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;
>
> (2) a full list of the articles used as components of such drug;
>
> (3) a full statement of the composition of such drug;
>
> (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;
>
> (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require;
>
> (6) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant;
>
> (7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and
>
> (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.[136]

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[135] Ibid.

[136] 21 USC § 360b(b).

Mandatory Reporting Requirements

Section 512(l) of the FDCA[137] authorizes the Secretary to require holders of an approved new animal drug application to "establish and maintain such records and make such reports to the Secretary" of information he may need "to determine or facilitate a determination, whether there is or may be grounds" for withdrawing approval for the drug because it may be unsafe or ineffective. Similarly, Section 512(j) of the FDCA[138] permits the Secretary to require safety and effectiveness reporting for new animal drugs under investigational use by experts.

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[137] 21 USC § 360b(l).

[138] 21 USC § 360b(j).

"POISONOUS OR DELETERIOUS SUBSTANCES" AND OTHER PROVISIONS

In addition to the previously identified provisions concerning potentially toxic chemicals, the FDCA regulates "poisonous or deleterious substances" in foods; "poisonous or deleterious substances" in packages containing foods, drugs, medical devices, and cosmetics; and medical devices.

Poisonous or Deleterious Substances[139]

Generally, a food is considered "adulterated" if it contains any poisonous or deleterious substance which "may render it injurious to health."[140] Foods with naturally occurring toxins are not considered adulterated "if the quantity of such substance in such food does not ordinarily render it injurious to health."[141]

When an added "poisonous or deterious substance" is required in production or cannot be removed through good manufacturing process, then the Secretary will issue a regulation setting a tolerance for the substance "to such extent as he finds necessary for the protection of public health."[142]

Poisonous or Deleterious Packaging[143]

Any food, drug, medical device, or cosmetic is considered "adulterated" if its container is "composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health."[144] Food-packaging materials may be considered food additives as discussed above in the text accompanying notes 55 to 59.

Medical Devices[145]

Under the FDCA, the term "device" is generally defined as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--

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[139] 21 USC §§ 342(a) and 346.

[140] 21 USC § 342(a).

[141] Ibid.

[142] 21 USC § 346.

[143] 21 USC §§ 342(a), 351(a), and 361(d).

[144] Ibid.

[145] 21 USC § 360c et seq.

> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.[146]

This is a much broader definition than had been in effect before the Medical Devices Amendment of 1976.[147] The purpose of that Amendment was to affect the regulation of medical devices, not really to alter the regulation of toxic chemicals.[148] However, such chemicals may be affected by the regulation of devices since they may be a "component" of devices. The medical devices provisions of FDCA permit the Secretary to ban the use of any medical device which presents "substantial deception or an unreasonable and substantial risk of illness or injury."[149] In addition, he may control the use of dangerous chemicals as components or ingredients of a Class III medical device (Class III devices require premarket approval), if the substance makes the device unsafe.[150]

"Medical device" provisions, like those for "new drugs" and "new animal drugs", require the holder of an approved application or investigational exemption to make reports of any information the Secretary may need to assure the safety and effectiveness of the device.[151]

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[146] 21 USC § 321(h). Familiar examples of devices are such things as pacemakers, X-ray machines, and IUDs.

[147] May 28, 1976, Pub. L. No. 94-295, 90 Stat. 575.

[148] The legislative history of the Medical Devices Amendment of 1976 is found in S. Rep. No. 94-33, 94th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 1070 (1976).

[149] 21 USC § 360f.

[150] 21 USC § 360e. Control of such chemicals as components or ingredients of a device is also possible under 21 USC § 360d, authorizing the Secretary to promulgate regulations for Class II devices, which are subject to performance standards.

[151] 21 USC § 360i.

FOOD, DRUG, AND COSMETIC ACT -- REGULATORY REVIEW

INTRODUCTION

The Food, Drug, and Cosmetic Act (FDCA) is the major statute granting authority for the operations of the Food and Drug Administration (FDA). The Act gives the FDA broad power to ensure that foods, drugs, medical devices, and cosmetics distributed in interstate commerce are safe for use by consumers.

In general, any product covered by the FDCA which is unsafe or contains an unsafe chemical component is considered "adulterated" and prohibited from distribution or sale. To protect against unknown risks, the statute also prohibits manufacturers from using or distributing a "food additive," "color additive," "pesticide chemical used in or on raw agricultural commodities," "new drug," "new animal drug" or "medical device" unless it use has been approved by the Secretary (see note 115 in the Statutory Review). Exhibit 3-4 lists the regulated substances and summarizes for each:

- the type of regulation authorized,
- the criteria for the standard,
- the basis for setting standards,
- the party with the burden of proof, and
- whether a risk/benefit analysis is required for regulation.

As amended, the FDCA is quite comprehensive; over 3000 pages of regulations interpret and implement the Act. For the most part, these regulations closely follow the provisions of the statute. The following sections explore the regulations as they concern the various categories of chemical substances governed by the Act:

• Pesticide Residues on Food	40 CFR 180
• Unavoidable Poisonous or Deleterious Substances	21 CFR 109
• Food Additives	21 CFR 193
• Color Additives	21 CFR 70
• New Drugs	21 CFR 300-460 (Subpart D)
• New Animal Drugs	21 CFR 556
• Cosmetics	21 CFR 700
• Medical Devices	21 CFR 860

EXHIBIT 3-4

OVERVIEW OF FOOD, DRUG, AND COSMETIC ACT REGULATORY AUTHORITY

Regulated Substances	Type of Regulation Authorized	Criteria for Standard	Standards Based on	Burden of Proof	Risk/Benefit Analysis
All Pesticide Chemical Residues unless generally recognized as safe (GRAS), or exempted by EPA	Allowable Tolerances (i.e., maximum permissible concentrations on raw agricultural commodities) • Zero tolerance may be set if the substance is an animal carcinogen	To the extent necessary to protect public health	• Health effects; • Economic, social, and environmental effects; • Usefulness of the chemicals; and • Total consumer exposure to same or similar substances	Petitioner for registration (under FIFRA) provides data in support of proposed tolerance or exemption showing the substance is safe for intended use	Yes
Poisonous or Deleterious Substances in any food IF: • Required in production, or • Cannot be avoided	• Allowable Tolerances and • Action Levels	To the extent necessary to protect public health	• Health effects; • Extent to which the presence of substance cannot be avoided; • Total consumer exposure; and • Expected technological or scientific changes	FDA must issue a formal tolerance or set an informal action level	No
All Food Additives except for those GRAS	• Certification of food additives, • Conditions and concentrations for safe use	• Reasonable certainty in the minds of competent scientists that the substance is not harmful under intended use conditions [21 CFR 170.3(i)]	• Probable consumption; • Cumulative toxic effects; • Appropriate safety factors used to extrapolate test data to human consumption; and • Cancer-inducing substances are generally prohibited	Petitioner provides data to show the proposed uses are safe	No

EXHIBIT 3-4

OVERVIEW OF FOOD, DRUG, AND COSMETIC ACT REGULATORY AUTHORITY

Regulated Substances	Type of Regulation Authorized	Criteria for Standard	Standards Based on	Burden of Proof	Risk/Benefit Analysis
All Color Additives except those exempted (No GRAS category)	• Certification, Conditions, and Concentrations for safe use • Batch Certification	Convincing evidence shows reasonable certainty that no harm will result from the intended use of the color additive	• Probable consumption; • Cumulative toxic effects; • Appropriate safety factors; • Any cancer-inducing substance (when ingested) is restricted	Petitioner provides data in support of proposed uses	No
New drugs; any drug intended for human use except for those GRAS, and pre-1938 drugs	• Approval of New Drug Applications (NDA), conditions for safe use • Certification or release for batches of insulin, antibiotics	• Safe and Effective as prescribed, recommended, or suggested in proposed labeling • Requires "substantial evidence"	• Effectiveness review including clinical investigations; • Therapeutic benefits outweigh health risks; and • Methods, facilities, and controls in manufacturing	Petitioner must prove safety and effectiveness	Yes

EXHIBIT 3-4

OVERVIEW OF FOOD, DRUG, AND COSMETIC ACT REGULATORY AUTHORITY

Regulated Substances	Type of Regulation Authorized	Criteria for Standard	Standards Based on	Burden of Proof	Risk/Benefit Analysis
New Animal Drugs except for those GRAS, or pre-1938	Certification, conditions for safe use, Pre-market approval	Same as for new drugs	• Effectiveness review including field investigations; • Methods, facilities, and controls in manufacturing • Human health risks through ingestion	Petitioner must prove safety and effectiveness	No
Cosmetics that contain poisonous or deleterious substances	Conditions for safe use, or Ban on substance	Any substance that may render it injurious to users under the prescribed, customary, or usual conditions of use	• Injury to users as prescribed in labeling; • Precautionary labeling • Manufacturing practices	FDA--No pre-market clearance required	No
Medical Devices	Classification, Special labeling, Conditions of use, Pre-market approval, Ban	Reasonable assurance to be safe and effective under prescribed conditions of use	• Effectiveness review; • Probable health benefits outweigh risks	Petitioner	Yes

PESTICIDE CHEMICALS

Chemical Substance Regulated

According to both the statute and the regulations,[152] a "pesticide chemical" is any substance which, alone or in combination with other substances, is a "pesticide" as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (40 CFR §180.1(k)).

In general, no raw agricultural commodity which bears or contains a "pesticide chemical" may be marketed in interstate commerce unless the Administrator of the EPA has set a tolerance (i.e. maximum permissible concentration) for the chemical on the commodity (21 USC §346a). Before the Administrator can set such a tolerance, however, the "pesticide" containing the "pesticide chemical" must be registered under FIFRA.

Unless the regulation fixing the concentration specifies otherwise, the allowable tolerances apply only to residues resulting from pre-harvest application of the pesticide (40 CFR §180.1(i)). Residues resulting from post-harvest application of a chemical are typically controlled by a food additive regulation at 21 CFR §193. (Most frequently, postharvest residues result from the use of pesticides in storage and processing areas or on the outside of bulk food packages. These regulations, and those generally concerning pesticide chemicals on processed foods are discussed later in the report under Food Additives.)

Approximately 270 pesticides or pesticide groups have been approved for use on raw agricultural commodities. They are listed, along with their maximum permissible concentrations on specific crops, at 40 CFR §180.101 through 180.379. Exhibit 3-5 contains an alphabetical listing of pesticides with approved tolerances.

Two categories of pesticide chemicals may be used on foods without a regulatory residue tolerance having been set--pesticide chemicals which are generally recognized as safe (GRAS) and those which have been specifically exempted from a tolerance by the Administrator. Regulations currently list 16 substances as GRAS and note that as a general rule, pesticide chemicals not contained on the list are not GRAS (40 CFR 180.2).

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[152] Almost all of the regulations implementing the FDCA are promulgated by the FDA. However, all of the powers granted to the FDA to establish tolerances for pesticide chemicals were transferred to the EPA by Reorganization Plan No. 3 of 1970. 35 FR 15623 October 6, 1970.

The second category of pesticide chemicals which do not require tolerances are those specifically exempted according to 21 USC §346a(c). That provision allows the Secretary (Administrator) to grant an exemption when a tolerance "is not necessary to protect the public health." Pursuant to that rule, over 600[153] "inert chemicals" listed in 40 CFR 180.1001(c) can be applied to growing crops or to raw agricultural commodities after harvest; those listed in 180.1001(d) may only be applied to growing crops; and those in 180.1001(e) may be applied to animals. In addition, the regulations list approximately 70 active pesticide chemicals which are exempt from the tolerance requirement (40 CFR 180.1001 through 180.1045).

All of the pesticide chemicals which have been exempted must be applied "in accordance with good agricultural practice." In other words, they must be applied by methods and in amounts commonly used when the exemption was granted.

Designation Criteria

The regulations do not expand on the statutory safety standard that must be met when a tolerance is set for a pesticide chemical. The statute mandates that the Secretary (Administrator) should set tolerances "to the extent necessary to protect the public health." (21 USC §346a(b)).

In prescribing the maximum allowable concentration of a chemical on a raw agricultural commodity, FDA must broadly consider the risks and the benefits of that chemical. The FDCA specifically states that FDA should consider the usefulness of the chemical and the necessity of the chemical for the production of an "adequate, wholesome, and economic food supply." Other ways in which the consumer may be affected by the same chemical or by related substances that are poisonous or deleterious must (21 USC §346a(b)) also be considered. Regulations implementing this last consideration stipulate that in addition to considering the amount of residue which a person may consume directly through the raw agriculatural products in his diet, consideration is always given to residues which may be consumed indirectly by ingestion of milk, eggs, meat, and poultry derived from animals fed the raw agricultural products (40 CFR 180.6).

In following these statutory and regulatory directions, the Administrator's decision concerning tolerances for "pesticide chemicals in or on raw agricultural products" is more broadly based than other safety decisions mandated by the FDCA. For these substances, the Administrator considers the economic, social, and environmental costs and benefits of using a pesticide.[154] Most other safety decisions under the FDCA involve only health considerations.

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[153] Some substances may have been counted twice. Pesticide chemicals appearing in 40 CFR 180.1001(c) or (d) may also be listed in 180.1001(e)

[154] Cooper, "The Role of Regulatory Agencies in Risk-Benefit Decision Making," 33 Food, Drug, and Cosmetic Law Journal 735 (1978).

At times, the Secretary may have to prescribe a zero tolerance level (i.e., no residue of the pesticide chemical) to insure that the treated commodities are safe for consumption. Such a tolerance may be set if (40 CFR 180.5):

> (a) a safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined, [or]
>
> (b) the chemical is carcinogenic or has other alarming physiological effects on test animals fed the substance.

The same section allows the Secretary to set a zero tolerance where accepted industry practice eliminates all residue of the chemical. He may set such a level if (40 CFR 180.5):

> (c) the chemical is toxic but it is normally applied at a time or in a matter that raw agricultural commodities will not normally bear residues, [or]
>
> (d) all residue of the chemical is normally removed through good agricultural practice such as washing or brashing or through weathering or other changes in the chemical itself, prior to introduction of the raw commodity into interstate commerce.

Finally, in considering whether a raw agricultural commodity bears an unsafe concentration of pesticide residues, "chemicals that cause related pharmacological effects will be regarded, in the absence of evidence to the contrary, as having additive deleterious action." (40 CFR 180.3). As an example, the regulations state that all chlorinated organic pesticides are considered to have related pharmacological effects.

Generally, if an agricultural commodity contains pesticide chemicals with related pharmacological effects, and analytical methods do not permit a precise quantitative determination of the amount of each chemical present, then the total residue from the related pesticides cannot exceed the lowest tolerance set for any individual pesticide in that group. However, when identification methods can precisely determine the amount of each chemical present, then a mathematical rule is followed. The actual concentration of each chemical is divided by the maximum permissible concentration, and the results are summed for each chemical. That sum cannot exceed one.

$$\sum \frac{\text{actual concentration}}{\text{permissible concentration}} \leq 1$$

A small number of exceptions to the general rule have been issued for specific chemicals with added deleterious effects. They are listed at 40 CFR 180.3(c) and (d).

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EXHIBIT 3-5

PESTICIDES WITH ESTABLISHED TOLERANCES

NAME	SECTION NUMBER
ACEPHATE	
ALACHLOR	180.108
ALDICARB	180.249
ALDRIN	180.269
ALLETHRIN (ALLYL HOMOLOG OF CINERIN I)	180.135
ALUMINUM PHOSPHIDE	180.113
AMETRYN	180.225
AMIBEN	180.258
4-AMINO-6-(1,1-DIMETHYLETHYL)-3-(METHYLTHIO) 1,2,4-TRIAZIN-5(4H)-ONE	180.266
4-AMINOPYRIDINE	180.332
AMMONIATES OF [ETHYLENEBIS(DITHIOCARBAMATO)] ZINC AND ETHYLENEBIS(DITHIOCARBAMIC ACID) BIMOLECULAR AND TRIMOLECULAR CYCLIC ANHYDROSULFIDES AND DISULFIDES	180.312
AMMONIUM SULFAMATE	180.217
AQUEOUS EXTRACT OF SEAWEED	180.188
ARAMITE	180.1042
ASULAM	180.107
ATRAZINE	180.360
BARBAN	180.220
BASIC COPPER CARBONATE	180.268
BASIC ZINC SULFATE	180.136
BENOMYL	180.244
BENTAZON	180.294
BENZADOX	180.355
(BHC)BENZENE HEXACHLORIDE	180.270
1,2-BENZISOTHIAZOLIN-3-ONE	180.140
6-BENZYLADENINE	180.1044
BIFENOX	180.376
BIPHENYL	180.351
1,1-BIS(*p*-CHLOROPHENYL)-2,2,2-TRICHLOROETHANOL	180.141
BORON	180.163
BROMACIL	180.271
3-(*p*-BROMOPHENYL)-1-METHOXY-1-METHYLUREA	180.210
BROMOXYNIL	180.250
BUTRALIN	180.324
sec-BUTYLAMINE	180.358
4-*tert*-BUTYL-2-CHLOROPHENYL METHYL METHYLPHOSPHORAMIDATE	180.321
N-BUTYL-N-ETHYL-α,α,α-TRIFLUORO-2,6-DINITRO-*p*-TOLUIDINE	180.295
CACODYLIC ACID	180.208
CALCIUM ARSENATE	180.311
CALCIUM CYANIDE	180.192
CAPTAFOL	180.125
CAPTAN	180.267
CARBARYL	180.103
CARBOFURAN	180.169
CARBON DIOXIDE	180.254
CARBOPHENOTHION	180.1049
CARBOXIN	180.156
CHLORBENSIDE	180.301
CHLORBROMURON	180.168
CHLORDANE	180.279
CHLORDIMEFORM	180.122
2-CHLOROALLYL DIETHYLDITHIOCARBAMATE	180.285
2-CHLORO-N,N-DIALLYLACETAMIDE	180.247
2-CHLORO-1-(2,4-DICHLOROPHENYL)VINYL DIETHYL PHOSPHATE	180.282
2-((4-CHLORO-6-(ETHYLAMINO)-*s*-TRIAZIN-2-YL)AMINO)-2-METHYLPROPIONITRILE	180.322
2-CHLORO-N-ISOPROPYLACETANILIDE	180.307
CHLORONEB	180.211
1-CHLORO-2-NITROPROPANE	180.257
p-CHLOROPHENOXYACETIC ACID	180.286
2-(*m*-CHLOROPHENOXY) PROPIONIC ACID	180.202
p-CHLOROPHENYL-2,4,5-TRICHLOROPHENYL SULFIDE	180.325
CHLOROPROPYLATE	180.256
2-CHLORO-1-(2,4,5-TRICHLOROPHENYL)VINYL DIMETHYL PHOSPHATE	180.218
6-CHLOROPICOLINIC ACID	180.252
CHLOROPROPYLATE	180.350
CHLOROSULFAMIC ACID	180.218
CHLOROTHALONIL	180.201
	180.275

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PESTICIDES WITH ESTABLISHED TOLERANCES (Continued)

NAME	SECTION NUMBER
CHLOROXURON	180.216
CHLORPYRIFOS	180.342
CIPC	180.181
COMBUSTION PRODUCT GAS	180.1051
COORDINATION PRODUCT OF ZINC ION AND MANEB	180.176
COPPER ARSENATE	180.193
COUMAPHOS	180.189
CYANO (3-PHENOXYPHENYL) METHYL-4-CHLORO-α-(METHYLETHYL) BENZENE ACETATE	180.379
CYCLOHEXIMIDE	180.336
CYPRAZINE	180.306
2,4-D	180.142
DALAPON	180.150
DAMINOZIDE	180.246
DDT	180.147
DDT RESIDUES IN CORN FORAGE, CORN FODDER, CORN SILAGE, CORN STOVER, AND SWEET CORN CANNERY WASTE	180.147a
DDT AND ITS RELATED DEGRADATION PRODUCTS IN MILK	180.147b
DECACHLOROOCTAHYDRO-1,3,4-METHENO-2H-CYCLOBUTA(cd)PENTALEN-2-ONE	180.287
DEMETON	180.105
DESMEDIPHAM	180.353
DIALIFOR	180.326
DICAMBA	180.227
DICHLOBENIL	180.231
DICHLONE	180.118
S-2,3-DICHLOROALLYL DIISOPROPYLTHIOCARBAMATE	180.277
1,1-DICHLORO-2,2-BIS(*p*-ETHYLPHENYL) ETHANE	180.139
2,4-DICHLORO-6-*o*-CHLOROANILINO-*s*-TRIAZINE	180.158
3,5-DICHLORO-N-(1,1-DIMETHYL-2-PROPYNYL) BENZAMINE	180.317
2,6-DICHLORO-4-NITROANILINE	180.200
4-(2,4-DICHLOROPHENOXY)BUTYRIC ACID	180.331
3-(3,5-DICHLOROPHENYL)-5-ETHENYL-5-METHYL-2,4-OXAZOLIDINEDIONE	180.380
2,4-DICHLOROPHENYL-*p*-NITROPHENYL ETHER	180.223
3',4'-DICHLOROPROPIONANILIDE	180.274
2,2-DICHLOROVINYL DIMETHYL PHOSPHATE	180.235
DICLOFOP METHYL	180.385
DIELDRIN	180.137
O,O-DIETHYL O-(2-DIETHYLAMINO-6-METHYL-4-PYRIMIDINYL) PHOSPHOROTHIOATE AND ITS OXYGEN ANALOG	180.308
N^3,N^3-DIETHYL-2,4-DINITRO-6-(TRIFLUOROMETHYL)-*m*-PHENYLENEDIAMINE	180.327
O,O-DIETHYL-S-[2-(ETHYLTHIO)ETHYL]PHOSPHORODITHIOATE	180.183
O,O-DIETHYL O-(2-ISOPROPYL-6-METHYL-4-PYRIMIDINYL) PHOSPHOROTHIOATE	180.153
O,O-DIETHYL O-[*p*-(METHYLSULFINYL)PHENYL] PHOSPHOROTHIOATE	180.234
O,O-DIETHYL O-2-PYRAZINYL PHOSPHOROTHIOATE AND ITS OXYGEN ANALOG	180.264
DIFENZOQUAT	180.369
DIFLUOROBENZENE	180.377
S-(O,O-DIISOPROPYL PHOSPHORODITHIOATE) OF N-(2-MERCAPTOETHYL) BENZENESULFONAMIDE	180.241
DIMETHOATE INCLUDING ITS OXYGEN ANALOG	180.204
O,O-DIMETHYL O-*p*-(DIMETHYL SULFAMOYL) PHENYL PHOSPHOROTHIOATE INCLUDING ITS OXYGEN ANALOG	180.233
3,5-DIMETHYL-4-(METHYLTHIO)PHENYL METHYLCARBAMATE	180.320
O,O-DIMETHYL S-(4-OXO-1,2,3-BENZOTRIAZIN-3 (4H)-YLMETHYL) PHOSPHORODITHIOATE	180.154
O,O-DIMETHYL S-(4-OXO-1,2,3-BENZOTRIAZIN-3 (4H)-YLMETHYL) PHOSPHORODITHIOATE AND/OR ITS METABOLITES IN MILK	180.154a
N, N-DIMETHYLPIPERIDINIUM CHLORIDE	180.384
DIMETHYL PHOSPHATE OF 3-HYDROXY-N,N-DIMETHYL-*cis*-CROTONAMIDE	180.299
DIMETHYL PHOSPHATE OF 3-HYDROXY-N-METHYL-*cis*-CROTONAMIDE	180.296
DIMETHYL PHOSPHATE OF α-METHYLBENZYL 3-HYDROXY-*cis*-CROTONATE	180.280
O,S-DIMETHYL PHOSPHORAMIDOTHIOATE	180.315
DIMETHYL TETRACHLOROTEREPHTHALATE	180.185
DIMETHYL (2,2,2-TRICHLORO-1-HYDROXYETHYL) PHOSPHONATE	180.198
2,6-DIMETHYL-4-TRIDECYLMORPHOLINE	180.372
2-(DIMETHYLAMINO)-5,6-DIMETHYL-4-PYRIMIDINYL DIMETHYLCARBAMATE	180.365
DIMETHYLFORMAMIDE	180.1046
4,6-DINITRO-*o*-CRESOL AND ITS SODIUM SALT	180.344
2,4-DINITRO-6-OCTYLPHENYL CROTONATE AND 2,6-DINITRO-4-OCTYLPHENYL CROTONATE	180.341
DINOSEB	180.281
DIOXATHION	180.171
DIPHENAMID	180.230
DIPHENYLAMINE	180.190
DIPROPETRYN	180.329
DIPROPYL ISOCINCHOMERONATE	180.143
DIQUAT	180.226
DIURON	180.106

EXHIBIT 3-5

PESTICIDES WITH ESTABLISHED TOLERANCES (Continued)

NAME	SECTION NUMBER
DODECACHLOROOCTAHYDRO-1,3,4-METHENO-2H-CYCLOBUTA[cd]PENTALENE	180.251
DODINE	180.172
ENDOSULFAN	180.182
ENDOTHALL	180.293
ENDRIN	180.131
EPN	180.119
ETHEPHON	180.300
ETHIOLATE	180.343
ETHION	180.173
ETHOFUMESATE	180.345
ETHOPROP	180.262
ETHOXYQUIN	180.178
5-ETHOXY-3-TRICHLOROMETHYL-1,2,4-THIADIAZOLE	180.370
S-ETHYL CYCLOHEXYLETHYLTHIOCARBAMATE	180.212
ETHYL 4,4-DICHLOROBENZILATE	180.109
S-ETHYL DIISOBUTYLTHIOCARBAMATE	180.232
S-ETHYL DIPROPYLTHIOCARBAMATE	180.117
ETHYLENE OXIDE	180.151
S-ETHYL HEXAHYDRO-1H-AZEPINE-1-CARBOTHIOATE	180.228
ETHYL 3-METHYL-4-(METHYLTHIO) PHENYL (1-METHYLETHYL)PHOSPHORAMIDATE	180.349
O-ETHYL S-PHENYL ETHYLPHOSPHORODITHIOATE	180.221
O-ETHYL O-4-(METHYLTHIO) PHENYL S-PROPYL PHOSPHORODITHIOATE	180.374
N-(1-ETHYLPROPYL)-3,4-DIMETHYL-2,6-DINITROBENZAMINE	180.361
S-[2-(ETHYLSULFINYL)ETHYL] O,O-DIMETHYL PHOSPHOROTHIOATE	180.330
FENTHION	180.214
FERBAM	180.114
FLUCHLORALIN	180.363
FLUOMETURON	180.229
FLUORINE COMPOUNDS	180.145
FLUORODIFEN	180.290
FOLPET	180.191
FORMETANATE HYDROCHLORIDE	180.276
GIBBERELLIC ACID	180.224
GLYODIN	180.124
GLYPHOSATE	180.364
GLYPHOSINE	180.354
GOSSYPLURE	180.1043
HEPTACHLOR AND HEPTACHLOR EPOXIDE	180.104
HEXACHLOROPHENE	180.302
HEXAKIS(2-METHYL-2-PHENYLPROPYL) DISTANNOXANE	180.362
HEXAZINONE	180.396
HYDROGEN CYANIDE	180.130
HYDROGENATED CASTOR OIL	180.1036
INORGANIC BROMIDE RESIDUES IN PEANUT HAY AND PEANUT HULLS	180.126a
INORGANIC BROMIDES OR TOTAL COMBINED BROMIDE RESULTING FROM FUMIGATION WITH ETHYLENE DIBROMIDE	180.146
INORGANIC BROMIDES RESULTING FROM FUMIGATION WITH METHYL BROMIDE	180.123
INORGANIC BROMIDES RESULTING FROM SOIL TREATMENT WITH ETHYLENE DIBROMIDE	180.126
INORGANIC BROMIDES RESULTING FROM SOIL TREATMENT WITH 1,2-DIBROMO-3-CHLOROPROPANE	180.197
INORGANIC BROMIDES RESULTING FROM SOIL TREATMENT WITH COMBINATIONS OF CHLOROPICRIN, METHYL BROMIDE, AND PROPARAGYL BROMIDE	180.199
INTERIM TOLERANCES	180.319
ISOPROPALIN	180.313
LEAD ARSENATE	180.194
LEPTOPHOS	180.345
LINDANE	180.133
LINURON	180.184
MAGNESIUM ARSENATE	180.195
MALATHION	180.111
MALEIC HYDRAZIDE	180.175
MANEB	180.110
MANGANOUS DIMETHYLDITHIOCARBAMATE	180.161
MAGNESIUM PHOSPHIDE	180.375
MEFLUIDIDE	180.386
MERCAPTOBENZOTHIAZOLE	180.160
N-(MERCAPTOMETHYL) PHTHALIMIDE S-(O,O-DIMETHYL PHOSPHORODITHIOATE) AND ITS OXYGEN ANALOG	180.261
METHANEARSONIC ACID	180.289
METHAZOLE	180.357
METHIDATHION	180.298
METHOMYL	180.253
METHOPRENE	180.359
METHOXYCHLOR	180.120

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PESTICIDES WITH ESTABLISHED TOLERANCES (Continued)

NAME	SECTION NUMBER
m-(1-METHYLBUTYL)PHENYL METHYLCARBAMATE and *m*-(1-ETHYLPROPYL)PHENYL METHYLCARBAMATE	180.255
2-METHYL-4-CHLOROPHENOXYACETIC ACID	180.339
4-(2-METHYL-4-CHLOROPHENOXY)BUTYRIC ACID	180.318
METHYL 3-[(DIMETHOXYPHOSPHINYL)OXY]BUTENOATE, *alpha* AND *beta* ISOMERS	180.157
6-METHYL-1,3-DITHIOLO-(4,5-b)QUINOXALIN-2-ONE	180.338
1-METHYL 2-((ETHOXY-[(1-METHYLETHYL) AMINO] PHOSPHINOTHIOYL)OXY) BENZOATE	180.387
4-(METHYLSULFONYL)-2,6-DINITRO-N,N-DIPROPYLANILINE	180.237
N-METHYL PYRROLIDONE	180.1047
METOLACHLOR	180.368
MINERAL OIL	180.149
NALED	180.215
α-NAPHTHALENEACETAMIDE	180.309
α-NAPHTHALENEACETIC ACID	180.155
2-(α-NAPHTHOXY)-N,N-DIETHYLPROPIONAMIDE	180.328
β-NAPHTHOXYACETIC ACID	180.148
N-1-NAPHTHYL PHTHALAMIC ACID	180.297
NEODECANOIC ACID	180.248
NICOTINE	180.167a
NICOTINE-CONTAINING COMPOUNDS	180.167
NITROGEN	180.1050
NOREA	180.260
NORFLURAZON	180.356
NOSEMA LOCUSTAE	180.1041
n-OCTYL BICYCLOHEPTENEDICARBOXIMIDE	180.367
2-*n*-OCTYL-4-ISOTHIAZOLIN-3-ONE	180.366
ORTHOARSENIC ACID	180.180
ORYZALIN	180.304
OVEX	180.134
OXADIAZON	180.346
OXAMYL	180.303
OXYTETRACYCLINE	180.337
PARAQUAT	180.205
PARATHION OR ITS METHYL HOMOLOG	180.121
PENTACHLORONITROBENZENE	180.291
PERFLUIDONE	180.165
PERMETHRIN	180.378
PHENMEDIPHAM	180.278
o-PHENYLPHENOL AND ITS SODIUM SALT	180.129
PHORATE	180.206
PHOSALONE	180.263
PHOSPHAMIDON	180.239
PICLORAM	180.292
PIPERONYL BUTOXIDE	180.127
POTASSIUM ARSENITE	180.334
PROFLURALIN	180.348
PROMETRYN	180.222
PROPARGITE	180.259
PROPAZINE	180.243
S-PROPYL BUTYLETHYLTHIOCARBAMATE	180.238
S-PROPYL DIPROPYLTHIOCARBAMATE	180.240
PYRAZON	180.316
PYRETHRINS	180.128
RONNEL	180.177
SCHRADAN	180.166
SECBUMETON	180.323
SESONE	180.102
SILVEX	180.340
SIMAZINE	180.213
SODIUM ARSENATE	180.196
SODIUM ARSENITE	180.335
SODIUM DEHYDROACETATE	180.159
SODIUM DIMETHYLDITHIOCARBAMATE	180.152
SODIUM SALT OF ACIFLUORFEN	180.383
SODIUM TRICHLOROACETATE	180.310
STREPTOMYCIN	180.245
SULPHENONE (*p*-CHLOROPHENYL PHENYL SULFONE)	180.112
TARTAR EMETIC	180.179
TDE (OR DDD)	180.187
TEBUTHIURON	180.390
TERBACIL	180.209
TERBUFOS	180.352
TERBUTHYLAZINE	180.333
TERBUTRYN	180.265

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PESTICIDES WITH ESTABLISHED TOLERANCES (Continued)

NAME	SECTION NUMBER
TERPENE POLYCHLORINATES	180.164
1,2,4,5-TETRACHLORO-3-NITROBENZENE	180.203
TETRADIFON	180.174
TETRAETHYL PYROPHOSPHATE	180.347
TETRAHYDRO-5,5-DIMETHYL-2(1H)-PYRIMIDINONE(3-(4-TRIFLUOROMETHYL)PHENYL)-1-(2-(4-(TRIFLUOROMETHYL)PHENYL)ETHENYL)-2-PROPENYLIDENE)HYDRAZONE	180.395
TETRAIODOETHYLENE	180.162
O,O,O',O'-TETRAMETHYL O,O'-THIODI-*p*-PHENYLENE PHOSPHOROTHIOATE	180.170
THIABENDAZOLE	180.242
2-(THIOCYANOMETHYLTHIO)BENZOTHIAZOLE	180.288
THIOPHANATE-METHYL	180.371
THIRAM	180.132
TOXAPHENE	180.138
S,S,S-TRIBUTYL PHOSPHOROTRITHIOATE	180.272
TRIBUTYL PHOSPHOROTRITHIOITE	180.186
S-2,3,3-TRICHLOROALLYL DIISOPROPYLTHIOCARBAMATE	180.314
TRICHLOROBENZYLCHLORIDE	180.273
2,3,6-TRICHLOROPHENYLACETIC ACID	180.283
TRICYCLOHEXYLTIN HYDROXIDE	180.144
TRIFORINE	180.382
TRIFLURALIN	180.207
2,3-5-TRIIODOBENZOIC ACID	180.219
2,2,5-TRIMETHYL-3-DICHLOROACETYL-1,3-OXAZOLIDINE	180.1052
3,4,5-TRIMETHYLPHENYL METHYLCARBAMATE AND 2,3,5-TRIMETHYLPHENYL METHYLCARBAMATE	180.305
TRIPHENYLTIN HYDROXIDE	180.236
ZINC PHOSPHIDE	180.284
ZINEB	180.115
ZIRAM	180.116

UNAVOIDABLE POISONOUS OR DELETERIOUS SUBSTANCES

Chemical Substances Regulated

Although the 1938 FDCA prohibited the use of poisonous or deleterious substances in food, it contained no provision requiring premarketing approval for food additives. As a result, food processors could prepare food with additives that had not been tested for safety. The federal government could only take actions when it could prove that the added substance was poisionous or deleterious. In 1958, the Food Additive Amendment reversed the required burden of proof; it provided that no processor could use a food additive unless he could prove that the substance was safe. Today, any additive that has not been approved as safe is automatically considered unsafe and banned from use in foods.

Reflecting the strength of the food additive amendment, regulations implementing 21 USC §346, the original FDCA provision dealing with poisonous or deleterious food additives, specify that such substances will generally be controlled by the newer food additives amendment (21 CFR 109.6). For instance, if no concentration of a substance is safe for ingestion, then it cannot be regulated as an approved food additive. However, if the substance is unavoidably present in foods because of wide-spread environmental contamination, the FDA will want to regulate the foods containing the substance. Since the food additives amendment cannot be used, the FDA will control the substances through tolerances or action levels issued under 21 USC §346.

Designation Criteria

The FDA may issue a tolerance permitting the presence of a poisonous or deleterious substance (21 CFR 109.6) when:

(1) "The substance cannot be avoided by good manufacturing practice,"

(2) "The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances," (emphasis added) and,

(3) "No technological or other changes are forseeable in the near future that might affect the appropriateness of the tolerance established."

If the first two conditions are met but forseeable technological changes may affect the level of the appropriate tolerance, then the prerequisites for etablishing a tolerance have not been met. Instead, the agency may set an informal "action level." The "action level" represents the point at which the FDA will proceed against foods containing unavoidable contaminants. If a formal tolerance for an added poisonous or deleterious substance has not been issued, any presence of the substance--even if it is an unavoidable substance--violates the provisions of the FDCA (21 USC §342(a)(C)). Section 336, however, allows the agency to refrain from prosecuting minor violations.

Action levels do not carry the same legal force as formal reguatory tolerances. Any food which contains residues above the appropriate tolerance level are automatically considered adulterated and barred from interstate commerce. The FDA only has to demonstrate that the tolerance has been exceeded. When proceeding against a food with residues that are higher than an action level, however, the FDA must defend its action level in court.

The FDA also uses action levels to protect against residues of pesticide chemicals not covered by an EPA tolerance. The EPA could actually set tolerance levels for unavoidable residues of pesticide chemicals under 21 USC §346, but they have not exercised that authority. Instead, if the pesticide chemical has not been regulated under the pesticide chemical amendment (pesticide chemicals in or on raw agricultural commodities) or under the food additive amendment (pesticide chemicals on processed foods), the FDA sets an action level. Such a situation occurs when the EPA withdraws the registration of a pesticide, but its widespread use in the past and a slow rate of decomposition mean that residues are unavoidably present in foods.

The safety standard used to regulate unavoidable poisionous or deleterious substances is not as strict as the standard used to regulate other food additives. In addition to considering the public health, the FDA must consider "the extent to which the presence of the substance cannot be avoided." (21 USC §346; 21 CFR 109.6)

FOOD ADDITIVES

Chemical Substances Regulated

Largely repeating the statutory definition, regulations identify "food additives" as "all substances...the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristic of food" (21 CFR 170.3). The regulations continue by emphasizing the broad sweep of the definition: even substances used in packages and containers are food additives if they migrate at all from the packaging to the food. Many substances are specifically excluded from the definition however. Substances which are generally recognized as safe (GRAS), "pesticide chemicals used in or on raw agricultural commodities" or used in the production, storage or transportation of raw agricultural products, "color additives", "new animal drugs," and substances approved for use before 1958 under the FDCA or under the Meat and Poultry Inspection Acts are all excluded from the term "food additive."

Designation Criteria

As with most other chemical substances covered by the Act, no food additive may be used in food unless a regulation has been promulgated by the FDA which sets safe conditions of use for the substance. In general, these regulations are issued in response to a request by a petitioner who wishes to use the additive. In submitting his application the applicant must provide information which among other things proves that the food additive will be safe. The petitioner does not have to prove that the additive will be safe under all circumstances. In fact, the regulations state, "It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance." (21 CFR 170.3(i)). Instead, a petitioner must demonstrate that "there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."

In reviewing safety data submitted by the applicant, the FDA considers the information and the investigative methods used in light of guidelines for establishing the safety of food additives published by the National Academy of Sciences - National Research Council (NAS-NRC) (21 CFR 170.20). The applicant does not need to exactly follow NAS-NRC guidelines, but he must use methods that provide results which are at least as reliable as those reasonably expected from the use of the suggested procedures. The applicant's investigation must also meet the good laboratory practice requirements specified in 21 CFR 58.

Safety Factor. When setting a tolerance (i.e. maximum permissible concentration) for the presence of a food additive in a food, the FDCA directs the FDA to consider safety factors used to extrapolate from animal experimentation data to safe human consumption levels (21 USC §348(c)(5)(C)). Regulations stipulate that the safety factor used is 100 to 1 (21 CFR 170.22). In other words, the maximum concentration of an additive in a food must be one percent or less of the amount which produces no harm in animals during long-term toxicological investigations. The 100 to 1 safety factor may be modified only if the petitioner demonstrates that another safety factor is appropriate. (This factor is inapplicable to cacinogenic food additives. The Delaney clause prohibits any concentration of a carcinogenic food additive (21 USC §348(c)(3)(A)).

The decision to approve a food additive is thus based on safety considerations. The FDA does not balance the economic benefits of the additive against its safety risks.

The focus on safety resulted from a Congressional desire to limit FDA's interference with the food market. Congress did not want to prevent a safe additive from gaining access to the market because the FDA doubted its utility or because its benefits were already available from another additive. Instead, all safe substances would be approved and the market would weigh the value of additives with similar effects.[155]

Regulations governing the use of food additives and setting maximum concentrations for their presence in foods span almost 300 pages in 21 CFR 172-178. By statute (21 USC §348(c)), these regulations also include the following conditions:

(1) restricting the additive to use on certain foods,

(2) specifying levels of purity for the additive,

(3) specifying the manner in which the additive can be applied, and

(4) mandating directions, labeling, or packaging requirements necessary to insure the safe use of the additive.

Once a tolerance has been set, any food which containes a greater concentration of the additive is automatically considered "adulterated" and prohibited from interstate commerce.

Additive Toxic Effects. As with pesticide chemicals, whenever two or more food additives that cause similar or related pharmacological consequences are present in a food, they are presumed to have an "additive toxic effect." (21 CFR 170.18) Where the individual concentration of each additive cannot be precisely measured, then the total concentration of the related additives cannot exceed the smallest separate tolerance. However, where the presence of each similar additive can be precisely measured, a proportional calculation is used to determine if the food contains an unsafe level of the related substances. The actual concentration of each additive is divided by its maximum permissible concentration. The sum of the resulting ratios cannot exceed one.

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[155] Merrill, "Risk-Benefit Decision Making by the FDA," 45 George Washington Law Review 994 (1977).

$$\sum \frac{\text{actual concentration}}{\text{maximum permissible concentration}} \leq 1$$

GRAS Food Additives

As explained above, substances which are generally recognized as safe (GRAS) are excluded from the definition of food additive (21 USC §321(s)). As a result, they may be used in foods even if they have not been approved by regulation. According to the statute, a substance may be classified as GRAS in either of two ways. First, scientific investigation may demonstrate to experts in the field of food additive safety that a substance is generally recognized as safe. Second, for substances used in foods before 1958, the year the Food Additive Admendment was passed, experts may generally recognize a substance is safe through "experience based on [its] common use in food." According to the FDA, when scientific procedure is used to show that a substance is GRAS, the "quantity and quality" of the evidence must be equal to the standards required to prove the safety of a food additive.[156] The classification of a substance as GRAS based on its common safe use in food prior to 1958 does not require the same level of evidence.[157]

The GRAS exception to the definiton of food additive was designed to avoid forcing manufacturers of substances which were already recognized as safe from having to submit to formal regulatory procedures. In addition, it was considered wasteful to require expensive safety investigations for substances whose safety had already been demonstrated through common use in foods.

Unfortunately, in the initial years after the passage if the Food Additive Amendment, many chemicals were added to the developing list of GRAS additives (21 CFR 170.30(e)) without an adequate review of their safety. As the use of additives in processed foods grew tremendously throughout the 1960's, several GRAS substances were discovered to be carcinogenic or toxic.[158]

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[156] 39 FR 34194 (September 23, 1974).

[157] Ibid.

[158] Malignant Neglect, Joseph Heghland, Marcia Fine, and Robert Boyle. 1980. Vintage Books.

Rising public and Congressional concern prompted the President to ask the FDA to begin a large scale review of food additives classified as GRAS. That review, begun ten years ago, is still continuing. Any ingredient which is reviewed and confirmed as GRAS is transferred from the original GRAS list at 21 CFR 182 to updated lists--21 CFR 184 if it is directly added to food, and 21 CFR 186 if it is an indirect additive which comes in contact with foods. (Indirect additives are often substances used in package wrappings which migrate in small concentrations to food they come in contact with.)

The regulations specifically state that these lists do not contain all GRAS substances (21 CFR 170.30). The large number of such ingredients makes a comprehensive list impractical. This is especially true for the "raw agricultural commodities and other substances of natural biological origin" which are used in processed food. As a result, the regulations recognize that:

> A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in Part 182, Part 184 or Part 186.1 of this chapter.

Ingredients which do not fit this category are considered to present a higher safety risk and are currently being examined through the food additive review. If a question arises as to whether any substance is GRAS, the FDA has administrative authority, subject to court review, to determine the status of the ingredient. (21 CFR 170.35(b)(4)). Similar authority concerning the status of new drugs has been upheld by the Supreme Court.[159]

As with food additives, the Commissioner may set conditions on the use of a GRAS substance. The FDA may, for instance, find that a substance is GRAS at or below a certain concentration on a food, when used for certain purposes, or when applied in certain ways. This authority stems from the agency's general authority to regulate food additives and exempt GRAS substances under 21 USC §348. If a manufacturer or processor does not comply with the conditions set by the FDA, then the ingredient is not GRAS for his intended use.[160] Instead, he must seek a new GRAS approval for his particular use or apply for a food additive regulation permitting that use.

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[159] Weinberger v. Hynson, Westcott, and Dunning, 412 US 609 (1973).

[160] 41 FR 53601 (December 7, 1976).

Interim Regulations. At times, new evidence raises questions about the safety of a food additive or GRAS substance. In such a case the FDA Commissioner may promulgate an "interim food additive regulation" permitting continued use of the product if it is "reasonably certain that the substance is not harmful and that no harm to the public health well result from the continued use of the substance." (21 CFR 180.1). The regulation may contain "whatever limitations the Commissioner deems to be appropriate under the circumstances." In addition, the manufacturer or processor must show within 60 days that studies investigating the safety of the substance have been undertaken.

Pesticide Chemicals on Processed Foods as Food Additives

The EPA is responsible for registering pesticides, regulating methods of application, and setting tolerance levels for pesticide residues on food. As explained in a previous section, pesticide tolerances on raw agricultural products are regulated under 21 USC §346a. Once the processing of the food begins, however, the FDA governs pesticide residues under the food additive section, 21 USC §348.

In general, regulations specify that if:

(1) a raw agricultural commodity conforms with EPA pesticide residue rules,

(2) good manufacturing practices are followed in processing to remove residues (ie. washing and peeling), and

(3) the pesticide concentration on processed food does not exceed the tolerance for the original raw agricultural commodity,

then the food will not be "adulterated." (21 CFR 170.19). Generally, foods that exceed the tolerance for their raw agricultural counterparts are adulterated and barred from interstate commerce.

Beyond these general rules, the Commissioner may further control a specific pesticide on a processed food through a food additive regulation. Approximately 60 pesticide chemicals are governed by specific regulations in 21 CFR 193. Many of these regulations control the application of pesticides to crops after they have been harvested or on wrappings and containers of bulk foods. Others govern the application of pesticide chemicals to surfaces inside processing plants. Finally, some raise the permissible residue tolerance on a processed food above that allowed in the raw product. Such a rule is usually promulgated to account for the natural increase in residue concentration that occurs when a raw agricultural commodity is dried. Some of the dried products affected, for instance, are raisins, prunes, and teas. These higher tolerances must be based on the safety standards required of other food additives.

The statutory and regulatory framework which divides authority between the FDA and the EPA has produced widely different safety standards for food additives versus pesticide chemicals. The FDA is primarily restricted to an examination of health risks in approving food additives. It examines the benefit of an additive only to ascertain that it serves the function claimed for it. The Delaney clause limits the approval process by specifying that no food additive may be approved if it is found to induce cancer. EPA, on the other hand, broadly considers the risks and benefits of a pesticide chemical used on a raw agricultrual product. (21 USC §346a). Safety is balanced against the usefulness of the chemical. Thus useful pesticide chemicals may be used, and their residues may be present on raw agricultural products, even if they are toxic or carcinogenic. The Delaney clause does not cover pesticide chemicals used on raw agricultural products.

Food additives, then, are regulated under much more stringent safety standards than pesticide chemicals, although they both may be present in food.

An added exception (21 USC §342(a)), extends the safety test for pesticide chemicals on raw agricultural products to pesticide chemical residues on processed food--even though the latter are statutorily defined as food additives. As previously noted, a processed food containing pesticide chemical residues is not considered adulterated if it meets the three requirements of 21 CFR 170.19. Under this provision, pesticide chemicals on processed foods--normally defined as food additives--do not have to meet the safety requirements for other food additives. Thus, a carcinogenic pesticide chemical residue may be allowed on a processed food, in contravention of the general thrust of the Delaney clause.

A final twist further complicates the safety standards. If the concentration of a pesticide residue on a processed food exceeds the corresponding maximum concentration for the raw agricultural commodity, then the safety standard exception from 21 USC §342(a) does not apply. Such a situation may occur with dried commodities like raisins or teas. Since they don't fit the exception, these residues are again treated as food additives. Their maximum permissible concentraton is set according to the traditional focus on safety and the Delaney clause which prohibits the use of any carcinogenic substance.

COLOR ADDITIVES

Chemical Substances Regulated

Both the statute and the regulations define a "color additive" as any material that "is a dye, pigment or other substance...[which]... when applied to a food, drug, or cosmetic, or the human body or any part thereof, is capable (alone or through reaction with another substance) of importing a color thereto." (21 USC §321(t), 21 CFR 70.3(f)). The regulations further specify that colors used to dye packaging are considered "color additives" if it is reasonably forseeable that they will transmit some of the color to the contents of the package. Natural food ingredients like cherries, that add their own color to foods they are mixed with, are not color additive unless they are added deliberately to color the other food. Beet juice, when used to impact a pink color, is a color additive. Finally, materials used solely for purposes other than coloring, and pesticides or nutrients used on produce are not considered "color additives."

Designation Criteria

Regulations concerning the safety of color additives closely resemble the rules dealing with food additives. For example, the FDA may not approve the use of a color additive unless "there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive." (21 CFR 70.3(i)). In addition, the regulations specify that color additives with similar pharmacological effects are presumed to have added toxicity. Food additives and pesticide chemicals whose effects are similar to those of a color additive are also considered to be toxicologically additive (21 CFR 70.11). Finally, the approval decision focuses on safety risks; it does not involve a risk/benefit analysis. As with food additives, the safety factor used to apply animal data to man is 100 to 1 (21 CFR 70.40).

As with other substances covered by the FDCA, the FDA Commissioner is authorized to prescribe broadly the conditions under which the color additive may be safely employed (21 CFR 70.42). Possible conditions include restrictions:

(1) limiting the additive to use on particular foods, drugs or cosmetics,

(2) specifying the maximum quantity of the additive that may used in any item,.

(3) mandating labeling, directions, or packaging which the additive must bear to assure its safety, and

(4) specifying which dilutants may be used with the additive.

The statute directs the FDA to consider the probable consumption of the additive before it issues a regulation allowing the color to be used. When examining such information, the FDA may discover that the color cannot be safely consumed under all of its proposed uses. In such a situation, regulations require the FDA to solicit input from all interested parties about how tolerances for the additive should be allocated among the competing needs. After analyzing the various viewpoints, the FDA will decide how to allocate the use of the color (21 CFR 70.45).

Regulations specifically mention the tests which will normally be sufficient to determine the safety of externally applied color additives (21 CFR 70.42(b)). The required tests include investigations of acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application. (These testing requirements are analyzed in Volume I.) Where any such test is not necessary, the FDA may waive it.

In implementing the Delaney clause the regulations differentiate between color additives that will be ingested and those that will not be (21 CFR 70.50). Whenever cancer is shown to be caused by a color additive that will be ingested the additive cannot be approved. Where the additive is not expected to be eaten, however, then the carcinogenicity of the substance will normally be tested by a route other than ingestion. Thus, a color additive which causes cancer when ingested may still be used in external drugs and cosmetics if its use in those products does not induce cancer.

There is no GRAS category for color additives; all must be approved by regulation before they can be used in foods, drugs, or cosmetics. In addition, to guarantee the quality of color additives, each "batch" of a color must be certified by the FDA. (21 USC §376(c)). Where such certification is not necessary to protect the public health, the FDA may exempt the color additive from the requirement. Approximately 150 color additives have been approved for use by the FDA. Two-thirds of the additives have been exempted from batch certification and are listed at 21 CFR 73. The other additives are separately listed in 21 CFR 74.

NEW DRUGS

Background

Before 1962, the FDCA required the manufacturer of any new drug to demonstrate the safety of the drug before it was distributed in interstate commerce. The statutory provisions were weak, however, because any New Drug Application (NDA) was automatically approved at the end of six months if the FDA had not issued an order declaring that the drug's safety had not been established. In strengthening the FDCA, the Drug Amendment of 1962 eliminated the automatic approval of drugs after six months. Today, no new drug can be marketed unless the FDA has specifically approved a NDA for the drug. In addition, the 1962 amendment now requires manufacturers to prove that their new drugs are both *safe and effective*.

Chemical Substances Covered

Regulations incorporate by reference the definition of "new drug" contained in the statute (21 CFR 310.3).[161] As previously stated, the Drug Amendment of 1962 prohibits the distribution of any "new drug" unless the FDA has approved a NDA certifying the drug as safe and effective. Regulations implementing the amendment insure that no "me-too" drugs introduced after January 1, 1962 will be marketed without FDA approval. Today, a product is considered a new drug requiring its own NDA if (21 CFR 310.3):

(1) it is comprised of any new substance regardless of whether it is an active or inactive ingredient,

(2) two or more drugs are combined into a new product, even if the individual drugs were previously approved,

(3) ingredients are combined in new proportions,

(4) it is used in a new way to diagnosis, cure, mitigate, treat, or prevent a disease, or to affect a structure or function of the body, or

(5) it is used in a new dosage, or administered differently, or any other condition of use recommended in the labelling is changed.

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[161] See 24 USC §321(p).

Actually, not every "new drug" requires a complete NDA. If the FDA is already satisfied that a basic drug is both safe and effective, it may require only an abbreviated new drug application (ANDA) for a new product. (21 CFR 314.1). For instance, a manufacturer's generic substitute for an already approved new drug may only require an ANDA. Because the issues are not in question, an ANDA does not need to contain the extensive safety and effectiveness proof generally required for a NDA. The ANDA must contain any information available to the applicant concerning adverse effects of the drug. As with a NDA, the applicant must provide adequate data about the bioavailability of the drug--the rate at which the active ingredients in the drug become available at the site of the drug action. (21 CFR 214.1(f)).

Where two or more drugs claim to be equivalents which can be used interchangeably, the FDA may establish a bioequivalence standard which the drugs must meet. (21 CFR 320.51). (Bioequivalent drugs have the same essential bioavailability.) Drugs with an approved NDA, as well as those with an approved ANDA, may have to meet the bioequivalent standard.

Approval Criteria

When submitting a new drug application, the petitioner must provide an exhaustive report describing among other things, the chemical properties, manufacturing techniques, safety, and effectivceness of the drug. (21 CFR 314.1). In addition, the NDA must include copies of the labeling proposed for use with the drug. No drug will be approved unless the NDA demonstrates that the drug is "safe [and effective] under the conditions prescribed, recommended, or suggested in the proposed labeling." (21 CFR 314.111).

Unlike food and color additives which are approved largely upon an evaluation of their safety risks, drugs are approved for use only after a balancing of therapeutic risks and benefits. "In practice, safe means that therapeutic benefits outweigh risks in a significant patient population.[162]

As a result of this balancing test, many toxic drugs have been approved by the FDA. Drugs used in chemotherapy, for instance, often have quite harmful effects. When used under the recommended conditions, however, the therapeutic benefits of the drugs outweigh their risks.

Every new drug must also prove, through substantial evidence, to have the effect it purports to have. Substantial evidence demands "adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." (21 CFR 314.111).

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[162] Cooper, "The Role of Regulatory Agencies in Risk-Benefit Decision Making," 33 Food, Drug, and Cosmetic Law Journal 759 (1978).

A further safety requirement is imposed on drugs containing insulin or antibiotics. Such drugs must receive FDA certification for every batch produced, as well as meeting the general safety and effectiveness requirements imposed on all drugs. (21 USC §356, 357; 21 CFR 429, 431). The FDA may exempt an antibiotic from batch certification if it is "not necessary" to insure safety and efficacy of use. (21 USC §357(c)).

NEW ANIMAL DRUGS

Chemical Substances Covered

Repeating the statutory definition, the regulations identify a "new animal drug" as "any drug intended for use in animals other than man, including any drug intended for use in animal feed but not including such animal feed." (21 CFR 510.3). Like the statute, regulations specifically exempt drugs which are:

(1) generally recognized as safe and effective (GRASE) and which have been used to a material extent under the conditions recommended on its labeling, or

(2) pre-1938 drugs which were subject to the Pure Food and Drug Act and whose label representations concerning conditions of use have not changed.

No new animal drug may be sold, distributed, or used in interstate commerce unless the FDA has approved a new animal drug application (NADA) which demonstrates that the substance is safe and effective. To avoid the type of problems that occurred when drug manufacturers tried to market their "me-too" drugs as GRAS, an animal drug is considered new, and requires the submission of another NADA whenever (21 CFR 510.3(i)):

(a) it is comprised of any new substance regardless of whether it is an active or inactive ingredient,

(b) two or more drugs are combined into a new product, even if the individual drugs were previously approved,

(c) ingredients are combined in new proportions,

(d) it is intended for use in a new species of animal,

(e) it is used in a new way to diagnoses, cure, mitigate, treat, or prevent a disease, or to affect a structure or function of the animal body, or

(f) it is used in a new dosage, or administered differencly, or any other condition of use recommended in the labeling is changed.

Animal feeds which contain a new animal drug are also governed by the FDCA and its regulations. Increasingly, animals grown for food production are being treated with drugs added to their feed. The drugs decrease producer's and consumer's costs by reducing losses from diseased animals and increasing yields. No feed containing a new animal drug may be marketed unless the FDA has approved the feed. As a first step toward that approval, feeds can only contain drugs that have already been approved as animal drugs by the FDA. (21 USC §360b; 21 CFR 558.4).

Designation Criteria

The regulations do not expand on the statutory safety standard prescribed for a new animal drug. They repeat the requirement that the FDA may not approve a NADA unless it finds that the applicant has demonstrated that the drug will be "safe and effective under its intended conditions of use" (21 CFR 514.105; 514.111). As with new drugs, the safety decision is based on a balance of the therapeutic risks and benefits of the drug.[163] The potential economic benefits of the drug in lowering the costs of meat and dairy products are not considered.

Although the applicant proposes conditions of use in his NADA, the FDA sets the final conditions in its regulation approving the drug. Such conditions may include allowable methods of use; dosage levels; withdrawal periods before slaughter; tolerances for the drug or its metabolites in edible products of food-producing animals; labeling or other requirements necessary to assure safe and effective use of drugs used in animal feeds; "or other use restrictions." (21 CFR 514.105).

Feeds containing new animal drugs will only be approved if the drug is used in the feed according to the conditions established by regulation when the drug was approved (21 USC §360b(M); 21 CFR 558.4). To further ensure the safety of feeds containing new animal drugs, the manufacturer of a drug intended for use in feed must have a written statement from the person receiving the drug that he holds an approved animal feed application issued by the FDA (21 CFR 510.7).

An additional safety standard is imposed on antibiotic new animal drugs. As provided by statute (21 USC §357), any antibiotic drug composed in any part of penicillin, streptomycin, chorteracycline, chloramphenicol, bacitracin, or any of their derivatives must also receive FDA certification for every batch produced in addition to meeting the general safety and effectivness tests. The FDA may exempt an antibiotic from batch certification if it is not necessary to insure that the drug "conforms to the standards of identity, quality, and purity" applicable to the drug.

Pursuant to these safety standards, the FDA has promulgated several major lists of regulations concerning approved new animal drugs. Drugs that do not require certification are contained in Parts 520-29 of the Code of Federal Regulations, Title 21. Antibiotic drugs are listed in Parts 539-555, and drugs used in animal feeds are contained in Part 558. In addition, tolerances for residues of animal drugs in food are detailed in Part 556.

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[163] Cooper, "The Role of Regulatory Agencies in Risk-Benefit Decision Making," 33 Food, Drug, and Cosmetic Law Journal 756 (1978).

COSMETICS

As previously explored in the statutory analysis, the FDA's authority to regulate hazardous chemicals in cosmetics is quite limited. If the government can prove that a cosmetic contains "any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling...or...as are customary or usual," then the cosmetic is deemed adulterated and barred from interstate commerce (21 USC §361). The FDA has no authority to require premarket clearance for cosmetic ingredients.

Under this limited authority the FDA has issued regulations prohibiting or severely restricting the use of the following cosmetic ingredients:

- Eggs in shampoo preparations
- Bithionol
- Mercury
- Vinyl Chloride in aerosols
- Halogenated Salicylanilides (tribromsalan--TBS, 3, 4', 5- tribromosalicylanilide, dibromosalan--DBS, 4', 5-dibromosalicylanilide, metabromsalan--MBS, 3, 5-dibromosalicylanilide, and 3, 3', 4, 5'-tetrachlorosalicylanilide--TCSA)
- Zirconium in aerosols
- Chloroform
- Chlorofluorocarbons

Those regulations appear at 21 CFR 700.

Despite these actions, a 1978 report by the GAO[164] concluded that about 125 chemicals listed in the Cosmetic, Toiletry, and Fragrance Association's Cosmetic Ingredient Dictiionary are suspected of causing cancer; about 25 are suspected of causing birth defects. In total, approximately 600 of the 2,750 ingredients reviewed are at least suspected of causing toxic effects. The chemicals are still used in cosmetics, however, because the ability of these ingredients to cause toxic effects through cosmetic use has not been determined.

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[164] Lack of Authority Hampers Attempts to Increase Cosmetic Safety, General Accounting Office, August 8, 1978. HRD-78-139.

Attempting to improve its ability to protect the public against potentially hazardous cosmetic ingredients, the FDA has issued several regulations requesting the cosmetic industry to provide information to the agency. First, any firm that engages in cosmetic manufacturing or packaging is requested to register with the FDA (21 CFR 700.10). Second, firms involved in cosmetic production are requested to file product ingredient statements (21 CFR 700.20). Such statements would identify the composition of each ingredient used in the cosmetic. Finally, industry firms are requested to file voluntary reports about any adverse or unusual cosmetic reactions about which the firm learns (21 CFR 700.30).

MEDICAL DEVICES

Substances Covered

The Medical Devices Amendment was designed to insure the safety and effectiveness of devices used "in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals." (21 USC §321 (h)). Familiar medical devices include pacemakers, x-ray machines, and IUDs. Although the amendment was not proposed to regulate potentially hazardous chemicals, any toxin which is contained in a "medical device" and which makes it unsafe, may be indirectly controlled by restrictions on the device.

Background

The statute creates three categories of medical devices (21 USC §360(c); 21 CFR 860.3). The safety and effectiveness of a Class I device can be assured through the general provisions of the statute dealing with labeling, adulteration, record-keeping, registration of producers, and the banning of hazardous devices. The safety and effectiveness of Class II devices can be assured only with additional provisions requiring the promulgation of an FDA approved performance standard. Finally, Class III devices are those which:

(a) present a potentially unreasonable risk of illness or injury, or which

(b) are used in supporting or sustaining human life, or are of substantial importance in preventing impairment of human health, and which cannot be safely regulated as Class I or II devices,

require premarket clearance by the FDA before they can be sold.

Approval Criteria

A Class III device will not receive approval for marketing unless the petitioner applying for clearance demonstrates "reasonable assurance that the device is safe [and effective] under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof "(21 USC §360e(d)(z)). While the regulations do not elaborate on the safety criteria used for the particular decision, they do clarify the health-based risk/benefit considerations generally applied to medical devices. In categorizing a device into Classes I, II, or III, for instance, the regulations specify that the object is safe when the probable health benefits of the device, when used as intended, outweigh any probable risks (21 CFR 860.7(d)).[165]

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[165] A similar test is used to determine effectiveness. A device is effective when a significant portion of the target population that uses the device according to its intended uses experiences clinically significant results (21 CFR 860.7(e)).

Another indirect method of regulating a toxic substance within a medical device is to ban the device under 21 USC §360(f). Applying the statutory standard, the regulation provides that the FDA may undertake such action whenever continued marketing of the device presents an "unreasonable and substantial risk of illness or injury." (21 CFR 895.21). In making its decision about whether the risk of illness or injury is substantial, the FDA will consider "whether the deception or risk...is important, material or significant in relation to the benefit to the public health from [the device's] continued marketing."

U.S. DEPARTMENT OF AGRICULTURE

The following reviews cover three statutes and regulations promulgated under these acts administered by the Department of Agriculture (USDA). The statutes include:

- Federal Meat Inspection Act
- Poultry Products Inspection Act
- Egg Products Inspection Act

The legal reviews and regulatory analysis that follow do not necessarily represent the official position of USDA. Moreover, this material has not been officially endorsed by the EPA as its understanding of USDA authority. The contractor, ICF Incorporated, is solely responsible for all analyses and interpretations.

FEDERAL MEAT INSPECTION ACT,[1] POULTRY PRODUCTS INSPECTION ACT,[2] AND EGG PRODUCTS INSPECTION ACT[3] -- STATUTORY REVIEW

INTRODUCTION

The Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA) provide for routine, mandatory federal inspection of slaughtering, meat-canning, salting, packing, or rendering operations, or similar establishments which slaughter certain livestock or poultry and process the products. The Acts also cover establishments and facilities which process eggs and products made from them. If the operator of a plant refuses to destroy any "adulterated" products whch have been condemned, the federal inspectors may be withdrawn from his facility. This sanction is a deterrrent, for most meat, poultry, or egg products cannot be sold in interstate commerce unless it has not been federally inspected. Criminal and civil actions may also be initiated concerning dealings in adulterated, misbranded, or uninspected products, and other violations of the Acts.

Two of the Acts, the FMIA and the PPIA, were updated and expanded by the Wholesome Meat Act (WMA) in 1967 and the Wholesome Poultry Act in (WPA) in 1968. Since 1906, meat and meat food products prepared for interstate or foreign commerce have been regulated under the Federal Meat Inspection Act. Poultry products prepared for interstate or foreign commerce have been similarly regulated since 1957 by the Poultry Products Inspection Act.

Despite these earlier Acts, a large amount of the nation's meat and poultry products was not being inspected. In 1967, for example, 15 percent of the animals commercially slaughtered in the United States for meat were regulated only by State laws because they were not prepared for interstate or foreign commerce.[4] Hearings before the Senate Agriculture and Forestry Commission indicated "that 25 percent of commercially prepared meat products [were] prepared without Federal inspection and to a significant degree [were] not subject to adequate State or local inspection."[5] The House Agriculture Committee found in 1968 that 13 percent of the poultry slaughtered in the U.S. each year was not subject to Federal inspection.[6]

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[1] 21 USC §601 et seq.

[2] 21 USC §451 et seq.

[3] 21 USC §1031 et seq.

[4] S. Rep. No. 799, 90th Cong., 1st Session, 1967, reprinted in 1967 U.S. Code and Cong. Ad. News 2190.

[5] Ibid.

[6] H.R. Rep. No. 1333, 90th Cong., 2nd Sess., 1968, reprinted in 1968 U.S. Code and Cong. Ad. News 3427.

To further consumer protection, a major thrust of the WMA and the WPA allowed the Secretary of Agriculture (USDA) to help initiate, cooperate with, and partially fund State inspection programs.[7] After an initial period, the Secretary was to extend the Federal Inspection program to meat or poultry prepared for intrastate commerce in any state which failed to develop or was not effectively enforcing requirements equal to federal requirements. Enacting this statute which covers products that are "in interstate or foreign commerce, or substantially affect such commerce," Congress exercised its broadest authority under the interstate commerce clause.[8]

The Federal Meat Inspection Act subjects foreign facilities which prepare meat for export to the United States to requirements at least equal to those applicable to domestic facilities.[9] Foreign poultry establishments are subject to similar regulation.[10]

The EPIA, enacted in 1970, subjected eggs and egg products to safety and inspection standards similar to those employed by the WMA and WPA. Congress found that "eggs and egg products are an important source of the Nation's total supply of food. . . . It is essential, in the public interest, that the health and welfare of consumers be protected by the adoption of measures precribed herein." This Congressional Statement of Findings cites destruction of markets, unfair competition, and consumer injury as ills that the Act is designed to avoid.[11]

SUBSTANCES COVERED

Each of the three Acts deals with the primary substance (i.e., poultry, meat, eggs) and the "products" of the substances. "Meat" is not defined, but "poultry" is defined as "any domesticated bird, whether live or dead,"[12] and "egg" is defined as "the shell egg of the domesticated chicken, turkey, duck, goose, or guinea".[13]

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[7] 21 U.S.C.A. §§ 454 (PPIA), 661 (FMIA).

[8] Ibid., §§ 451 (PPIA), 602 (FMIA).

[9] Ibid., § 620.

[10] See Ibid., § 466, 9 CFR 381, Subpart T.

[11] Ibid, § 1031. This parallels the Congressional findings for the FMIA (§ 451) and the FMIA (§ 602).

[12] Ibid., §453(e).

[13] Ibid., §1033(g).

The "products" of these three substances are defined in the same general manner:

- "Meat food product" includes any product capable of use as human food and which is made entirely or partially from the meat or any other part of the carcass of cattle, sheep, swine, goats, or equines. The Secretary may exempt (1) a product which has a "relatively small proportion" (undefined by the statute) of meat or other portions of the carcass, or (2) products which "historically have not been considered by consumers as products of the meat food industry under such conditions as he may prescribe to assure that the meat or portions of the carcass used in the product are not adulterated and that such exempted products are not represented as meat food product.[14]

- "Poultry product" includes all or a portion of the poultry carcass and any product that is wholly or partially composed of the poultry carcass or a portion of it. As with the definition for "meat food product", the Secretary may exempt a product from the definition in a *de minimis* situation and where consumers have historically not regarded this product as coming from the poultry food industry under such conditions as he may prescribe to assure that the exemption does not result in the use of adulterated poultry ingredients and that exempted products are not represented as poultry products.[15]

- "Egg products" include "any dried, frozen, or liquid eggs, with or without added ingredients." The same two exemption situation exist, subject to the same kind of regulatory action by the Secretary of Agriculture.[16]

One reported case[17] deals with the exemption from the definition of "poultry product." At the time this case was decided, there was different statutory language that authorized an exemption: *"(U)nless exempted by the Secretary*, any human food product consisting of any eligible part of poultry separately or in combination with other ingredients" was considered a poultry product (emphasis added). The Court considered the statutory exemption to have "been drawn with a view to relieving the Secretary of the unduly burdensome task of supervising the manufacture and sale of products that have little poultry meat."[18]

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[14] *Ibid*., §601(j).

[15] *Ibid*., §453(f).

[16] *Ibid*., §1033(f).

[17] *Borden Co. v. Freeman*, 256 F. Supp. 592 (D. N.J., 1966), *aff'd* 396 F.2d 404, *cert. denied*, 386 U.S. 369.

The regulation in question had exempted products (this particular litigation concerned soups) with less than 2% poultry meat and, among other things, that had no false or misleading labeling. The court found the regulation to be

> "a reasonable definition" of what products are to be considered exempt from the term "poultry product." This regulation is "a sensible exercise of judgment" by the Secretary; for it provides for the best possible workable compromise between the policies of (1) insuring against the use of false or misleading labels and (2) allowing the Secretary to divest himself of jurisdiction over products whose poultry content is minimal.[19]

Although the case does not specifically address meat or egg products, the parallels between the three Acts suggest that the exemption under all three Acts may receive similar treatment from the courts.

It is not clear, however, that the Court based its approval solely on the 2% figure or on the fact that of soups with poultry ingredients, over 90% were still included in the defintion of "poultry product."[20] If it is possible to draw a general proposition from one case, there appears to be two criteria that must be satisfied by an exemption based on "relatively small proportion": (1) the percentage of the regulated substance in the product must be low (it is not clear that 2% is a ceiling), and (2) the percentage of the general product (e.g., poultry soups) that are exempted cannot be too large (it is not clear that 90% still subject to regulation is a floor).

HARM TO BE AVOIDED

One of the major concerns of these Acts is to protect the public from adulterated food products. Each Act sets forth criteria, only one of which must be met, for a covered product to be considered adulterated:

- A product is adulterated if it bears or contains a poisonous or deleterious substance that may make the product injurious to health. If the poisonous or deleterious substance is not an added substance, however, the product will not be adulterated if the quantity of the substance "does not ordinarily render [the product] . . . . injurious to health."[21]

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[18] Ibid., p. 598.

[19] Ibid., p. 600.

[20] Ibid., p. 603.

- A product is adulterated if the Secretary considers it unfit for human consumption due to an added poisonous or added deleterious substance borne on or contained in the product.[22]

- A product is adulterated if it is wholly or partially a raw agricultural commodity and bears or contains a pesticide determined to be unsafe under 21 U.S.C.A.
  § 346a (Food, Drug and Cosmetic Act (FDCA)), if it contains a *food additive* that is unsafe under § 348 (FDCA), or if it contains a *color additive* that is unsafe under § 376 (FDCA). Even if a substance within these three categories is considered safe under the FDCA, its presence in or on a product will make the product adulterated if the Secretary has promulgated regulations prohibiting the use of the substance.[23]

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[21] 21 U.S.C.A. §§ 453(g)(1)(A) (PPIA), 601(m)(1) (FMIA), and 1033(a)(1) (EPIA) (emphasis added).

[22] *Ibid*., §§ 453(g)(2)(A) (PPIA), 601(m)(2)(A) (FMIA), and 1033(a)(2)(A) (EPIA).

[23] *Ibid*., §§ 453(g)(2)(B)-(D) (PPIA), 601(m)(2)(B)-(D) (FMIA), and 1033(A)(2)(B)-(D) (EPIA). The Senate report notes the following differences between the WMA and the FDCA:

- Under § 601(m)(2)(C) "an article is adulterated only if it *bears* or *contains* an unsafe food additive. . . . The [FDCA] . . . also applies to an article that *is* an unsafe food additive."

- "A proviso contained in the [FDCA] . . . with respect to pesticide chemical residue in or on processed food made from raw agricultural commodities is omitted from new section . . . [601](m)(2)(C) to give the Secretary of Agriculture more discretion in making determinations under section . . . [601](m)(2)(C) with respect to the safety of residues in processed meat products."

- At the end of section . . . [601](m)(2), a proviso is added to allow the Secretary of Agriculture to impose more stringent restrictions for pesticide chemicals, food additives and color additives in or on meat products subject to the new act than are imposed by the Secretary of HEW under the FDCA.

S. Rep. No. 799, *op. cit*., p. 2195. The FDCA is analyzed in a companion paper in this volume.

- A product is adulterated if it wholly or partially consists of a decomposed, putrid, or filthy substance, or is for any other reason unsound, unhealthy, unwholesome, or otherwise unfit for human food.[24]

- A product is adulterated if it has been packed, prepared, or held under unsanitary conditions so that it [either may have become contaminated with filth or] may have become injurious to health.[25]

- A product is adulterated if it is wholly or partially composed of an animal that has died other than by slaugher or, in the case of eggs, the product is wholly or partially composed of eggs subjected to incubation.[26]

- A product is adulterated if its container is wholly or partially composed of a poisonous or deleterious substance that may make the contents injurious to health.[27]

- A product is adulterated if it has been intentionally subjected to radiation, unless the radiation has been exempted under § 348 of the FDCA.[28]

Reported cases under the FMIA have interpreted the term "adulterated." In a case dealing with excess fat, a meat food product was alleged to be adulterated because fat had "been substituted in part for beef or . . . added so as to reduce the quality or strength of the meat food product."[29/] The Court, in finding that the product was adulterated, noted that

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[24] Ibid., §§ 453(g)(3) (PPIA), 601(m)(3) (FMIA), and 1033(a)(3) (EPIA).

[25] Ibid., §§ 453(g)(4) (PPIA), 601(m)(4) (FMIA), and 1033(a)(4) (EPIA).

[26] Ibid., §§ 453(g)(5) (PPIA), 601(m)(5) (FMIA), and 1033(a)(5) (EPIA).

[27] Ibid., §§453(g)(6) (PPIA), 601(m)(6) (FMIA), and 1033(a)(6) (EPIA).

[28] Ibid., §§ 453(g)(7) (PPIA), 601(m)(7) (FMIA), and 1033(a)(7) (EPIA). Note that each of the Acts contains a provision related to "economic adulteration"--essentially making a product appear better than it is. See ibid., §§ 453(g)(8) (PPIA), 601(m)(8) (FMIA), and 1033(a)(8) (EPIA). Note also that the FMIA, § 601(m)(9), has a final criterion that the other two Acts lack: margarine containing animal fat is deemed adulterated if any of its raw materials consisted in whole or in part of any filthy, putried, or decomposed substance.

> [a]n adulterated product not only includes one not fit to be eaten, "but also one to which almost anything has been added or extracted to make the product seem better than it actually is." (quoting U.S. v. 500 Pounds, etc., Veal and Beef, 319 F. Supp. 966, 967 (N.D. Cal., 1970).[30/]

In the MDM case,[31/] the United States District Court for D.C. enjoined the Department of Agriculture from giving further effects to an intended regulation prescribing a standard for "mechnically deboned meat (MDM)." The court held that the Department did not comply with the Administrative Procedures Act in issuing the standards without public notice and public comment. The Court also rejected the Government's argument that the bone particles in MDM were really part of the meat[32/] and therefore, MDM-containing products could not be adulterated. In this regard, the court held that "meat" did not include MDM because it contained bone particles. The Court, however, noted that the record before it was an inadequate basis for determining whether the use of MDM reduced the quality of meat food products (such reduction would violate the economic adulteration provision of section 601(m)(8)). In addition, the Court noted that the Secretary was required

> to have made a determination that there is no substantial possibility that the presence of bone particles in a concentration of .45% in processed products containing MDM could harm the health of those ingesting the product.[33/]

[29/] U.S. v. 2623 Pounds, More or Less, of Veal and Beef, 336 F. Supp. 140, 143 (N.D. Cal., 1971), supplemented 332 F. Supp. 1091. In addition to the "adulteration" issue, this case dealt with labeling issues.

[30/] Ibid.

[31/] Community Nutrition Institute v. Butz, 420 F. Supp. 751, 755 (D.C.D.C., 1976).

[32/] The Secretary's argument was based on his regulation (9 CFR 301.2(tt)) that, in part, provides that meat includes "the portions of bone, skin, sinew, nerve, and blood vessels which normally accompany the muscle tissue and which are not separated from it in the process of dressing." The Court, however, read this not to include "[g]round up bits of bone entering the meat in the mechanical deboning process, or entering a processed meat with the addition of MDM. . ." Ibid., p. 755

[33/] Ibid.

The Court indicated three additional factors relevant to a determination that MDM did not adulterate products in which it is used:

- A finding that the bone particles are not detectable by touch or taste does not satisfy the requirements of section 601(m)(1) (see the first criteria discussed under "Harm to be Avoided").
- Nutritional benefit alone is not a sufficient reason for finding (under section 601(m)(1)) that the product is not injurious to health.
- MDM is considered an adulterated product until the Secretary considers several specific questions (raised by the medical literature but not addressed by the Secretary) concerning the medical effects of the product.[34]

REPORTING REQUIREMENTS

The Meat, Poultry, and Egg Products Inspection Acts do not specifically require the regulated businesses to report incidents of contaminations relating to their products. However, any sale, transportation or offer for sale or transportation or use of such products may trigger criminal penalties or other enforcement actions under the Acts. Federal inspectors are routinely present in plants where slaughtering, preparing and packaging occurs.[35] They carefully inspect facilities, products and operations. In addition, random samples of the industries' products are analyzed under USDA's monitoring programs. Finally, commercial sellers, buyers, slaughterers, packagers, processors, renderers, warehouse operators, and transporters must maintain "such records as will fully and correctly disclose all transactions involved in their business."[36] They must allow authorized representatives of the Secretary access to their facilities and the opportunity to examine their facilities, inventory and records.

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[34] *Ibid*., p. 756.

[35] Several small plants often share an inspector who splits his time between them.

[36] 21 U.S.C.A. §§460(b) (PPIA), 642(a) (FMIA), 1040 (EPIA). The EPIA reporting requirements apply to "transporting, shipping, or receiving . . . in commerce or holding such articles so received, and all egg handlers. . ."

FEDERAL MEAT INSPECTION ACT, POULTRY PRODUCTS INSPECTION ACT, AND EGG PRODUCTS INSPECTION ACT--REGULATORY REVIEW

INTRODUCTION

Regulations promulgated under these acts reflect the specific outline of the statutes themselves. In all three cases, Congress prohibits the sale, transport, or offer for sale or transport of any products which are misbranded, adulterated, or have not been handled, processed and sold in accordance with the provisions of the act.

Regulations under the Acts, as amended by the Wholesome Meat Act, the Wholesome Poultry Products Act, and the Egg Products Inspection Act, were first promulgated in 1970 for Meat Products,[37] 1972 for Poultry Products,[38] and 1971 for Egg Products.[39]. The regulations contain mandatory inspection requirements and other provisions designed to prevent the sale or distribution of "adulterated" and misbranded products.

The regulations primarily complete the definition of "adulterated" given in the statutes by supplying the criteria for evaluation of facilities, product quality, packaging, processing, and shipment of meat, poultry, and egg products. The regulations primarily deal with required procedures, rather than the designation of certain products or substances considered hazardous. The next three sections discuss the meat, poultry, and egg product regulations.

MEAT INSPECTION

The Mandatory Meat Inspection regulations are published in 9 CFR 301-335. The regulations have specific requirements for procedures involved in processing meat from the live animal on to the cooking, labeling, and packaging of meat products. The main section applicable to this analysis is Part 318.7 dealing with chemical substances used in the preparation of meat products. Meat products are considered "adulterated"[40] and may not be sold, if they contain additives (as defined by the Food, Drug, and Cosmetic Act (FDCA), in quantities considered unsafe under the FDCA, or contain other substances not approved by the Food Safety and Quality Service of USDA.

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[37] 35 FR 15554 October 3, 1970. See 9 CFR 301 to 335.

[38] 37 FR 9706 May 16, 1972. See 9 CFR 381.

[39] 36 FR 9814 May 26, 1971. See 7 CFR 2859.

[40] 9 CFR 301.2(aa) Definition of adulterated. See statutory review.

Additives are initially evaluated by FDA, but USDA may add restrictions concerning FDA approved additives or prohibit such additives in some products. 9 CFR 318.7 contains a list of chemical substances used as additives, products they are used for, and allowable concentrations of those used in the processing of meat products (Exhibit 4-1). These include such things as binders, antioxidants, flavorings, fillers, emulsifiers, and curing agents. Part 318.7(b) also contains a special discussion of sodium nitrite, ascorbate, and isoascorbate in bacon, focusing on testing requirements to determine and limit nitrosamine (a suspect carcinogen) levels after cooking.

POULTRY PRODUCTS

Mandatory Poultry Products Inspection Regulations are published at 9 CFR 381. They are similar to the Meat Products Inspection regulations, describing various phases of poultry processing. Part 381.47 contains a list of substances, including uses and amounts, allowed for the processing of poultry products (Exhibit 4-2).

EGG PRODUCTS

Regulations promulgated under the Egg Products Inspection Act of 1970 are published at 7 CFR 2859. They require inspection of all egg facilities, including production, processing and packaging of egg products. There is no listing of allowed or prohibited additives or tolerances for contaminants in egg products.

EXHIBIT 4-1

FOOD SUBSTANCES: MEAT PRODUCTS a/

Class of substance	Substance	Purpose	Products	Amount	
Anticoagulants	Citric acid, sodium citrate	To prevent clotting	Fresh blood of livestock.	0.2 percent—with or without water. When water is used to make a solution of citric acid or sodium citrate added to blood of livestock, not more than 2 parts of water to 1 part of citric acid or sodium citrate shall be used.	
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups	10 parts per million.	
			Rendered fats	Do.	
			Curing pickle	50 parts per million.	
Antioxidants and oxygen interceptors	BHA (butylated hydroxyanisole)	To retard rancidity	Dry sausage	0.003 percent based on total weight	006 percent in combination.
	BHT (butylated hydroxytoluene)	do	do	do	
	Propyl gallate	do	do	do	
	TBHQ (tertiary butylhydroquinone).	do	do	do	0.006 percent in combination only with BHA and/or BHT
	BHA (butylated hydroxyanisole).	do	Rendered animal fat or a combination of such fat and vegetable fat.	0.01 percent	0.02 percent in combination
	BHT (butylated hydroxytoluene).	do	do	do	
	Glycine	do	do	do	
	Propyl gallate	do	do	do	
	Resin guaiac.	do	do	do	
	TBHQ (tertiary butylhydroquinone)	do	do	do	0.02 percent in combination only with BHA and/or BHT
	Tocopherols	do	do	0.03 percent. A 30 percent concentration of tocopherols in vegetable oils shall be used when added as an antioxidant to products designated as "lard" or "rendered pork fat."	
	BHA (butylated hydroxyanisole)	do	Fresh pork sausage, brown and serve sausages, Italian sausage products, pregrilled beef patties, and fresh sausage made from beef or beef and pork	0.01 percent based on fat content	0.02 percent in combination based on fat content
	BHT (butylated hydroxytoluene)	do	do	do	
	Propyl gallate	do	do	do	

a/ 9CFR 318.7

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount	
	TBHQ (tertiary butylhydroquinone).	To retard rancidity	Fresh pork sausage, brown and serve sausages, Italian sausage products, pregrilled beef patties, and fresh sausage made from beef or beef and pork.	0.01 percent based on fat content	0.02 percent in combination only with BHA and/or BHT based on fat content.
	BHA (butylated hydroxyanisole).	do	Dried meats	0.01 percent based on total weight	0.01 percent in combination
	BHT (butylated hydroxytoluene)	do	do	do	
	Propyl gallate	do	do	do	
	TBHQ (tertiary butylhydroquinone)	do	do	do	0.01 percent in combination only with BHA and/or BHT
Binders	Algin	To extend and stabilize product.	Breading mix; sauces	Sufficient for purpose	
	Carrageenan	do	do	Do	
	Carboxymethyl cellulose (cellulose gum).	do	Baked pies	Do	
	Gums, vegetable	do	Egg roll	Do	
	Methyl cellulose	To extend and to stabilize product (also carrier)	Meat and vegetable patties.	0.15 percent	
	Isolated soy protein	To bind and extend product	Sausage, as provided for in Part 319 of this subchapter	2 percent.	
	do	do	Imitation sausage, nonspecific loaves, soups; stews	Sufficient for purpose	
	Sodium caseinate	do	do	Do	
	Whey (dried)	do	do	Do	
	Xanthan gum	To maintain uniform viscosity, suspension of particulate matter, emulsion stability, freeze-thaw stability	Meat sauces, gravies or sauces and meats, canned or frozen and/or refrigerated meat salads, canned or frozen meat stews, canned chili or chili with beans, pizza topping mixes and batter or breading mixes	Do	
Bleach	Hydrogen peroxide	To remove color	Tripe (substance must be removed from product by rinsing with clear water)		
Catalysts (substance must be eliminated during process)	Nickel	To accelerate chemical reaction	Rendered animal fats or a combination of such fats and vegetable fats	Do	
	Sodium amide	Rearrangement of fatty acid radicals	do	Do	
	Sodium methoxide	do	do	Do	
Coloring agents (natural)	Alkanet, annatto, carotene, cochineal, green chlorophyll, saffron and turmeric	To color casings or rendered fats; marking and branding product	Sausage casings, oleomargarine, shortening, marking or branding ink on product	Sufficient for purpose (may be mixed with approved artificial dyes or harmless inert material such as common salt and sugar)	

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
Cooling and retort water treatment agents.	Sodium tripolyphosphate	To prevent staining on canned goods	Any	0.05 percent.
	Zinc oxide	do	do	0.01 percent.
	Zinc sulfate	do	do	Do.
Curing accelerators: must be used only in combination with curing agents.	Ascorbic acid	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic acid	do	do	Do.
	Glucono delta lactone	To accelerate color fixing.	Cured, comminuted meat or meat food product.	8 oz to each 100 lb of meat or meat byproduct.
			Genoa salami	16 oz to 100 lb of meat (1.0 percent).
	Sodium acid pyrophosphate.	do	Frankfurters, wieners, vienna, bologna, garlic bologna, knockwurst, and similar products.	Not to exceed, alone or in combination with other curing accelerators, the following: 8 oz in 100 lb of the meat, or meat and meat byproducts, content of the formula; nor 0.5 percent in the finished product.
	Sodium ascorbate	To accelerate color fixing or preserve color during storage.	Cured pork and beef cuts, cured comminuted meat food product.	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb meat or meat byproduct; 10 percent solution to surfaces of cured cuts prior to packaging. (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Sodium erythorbate	do	do	Do.
	Citric acid or sodium citrate.	do	do	May be used in cured products or in 10 percent solution used to spray surfaces of cured cuts prior to packaging to replace up to 50 percent of the ascorbic acid, erythorbic acid, sodium ascorbate, or sodium erythorbate that is used.
Curing agents	Sodium or potassium nitrate.	Source of nitrite	Cured products other than bacon. Nitrates may not be used in baby, junior, and toddler foods.	7 lb to 100 gal pickle; 3½ oz to 100 lb meat (dry cure); 2¾ oz to 100 lb chopped meat except that nitrate may be used in bacon only in accordance with paragraph (b) of this section.
	Sodium or potassium nitrite. (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly.)	To fix color	Cured products. Nitrites may not be used in baby, junior, or toddler foods.	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb meat (dry cure); ¼ oz to 100 lb chopped meat and/or meat byproduct. The use of nitrites, nitrates, or combination shall not result in more than 200 parts per million of nitrite, calculated as sodium nitrite, in finished product.

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
Denuding agents, may be used in combination. Must be removed from tripe by rinsing with potable water	Lime (calcium oxide, calcium hydroxide)	To denude mucous membrane	Tripe	Sufficient for purpose
	Sodium carbonate	do	do	Do
	Sodium gluconate	do	do	Do
	Sodium hydroxide	do	do	Do
	Sodium metasilicate	do	do	Do
	Sodium percarbonate	do	do	Do
	Trisodium phosphate	do	do	Do
Emulsifying agents	Acetylated monoglycerides	To emulsify product	Shortening	Do
	Diacetyl tartaric acid esters of mono and diglycerides	do	Rendered animal fat or a combination of such fat with vegetable fat	Do
	Glycerol-lacto stearate, oleate, or palmitate	do	do	Do
	Lecithin	To emulsify product (also as antioxidant)	Oleomargarine, shortening	Do
	Mono and diglycerides (glycerol palmitate, etc.)	To emulsify product	Rendered animal fat or a combination of such fat with vegetable fat	Sufficient for purpose in lard and shortening; 0.5 percent in oleomargarine
	Polyglycerol esters of fatty acids (polyglycerol esters of fatty acids are restricted to those up to and including the decaglycerol esters and otherwise meeting the requirements of § 121.1120(a) of the Food Additive Regulations)	do	Rendered animal fat or a combination of such fat with vegetable fat when use is not precluded by standards of identity or composition	Sufficient for purpose
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate)	do	Shortening for use in nonstandardized baked goods, baking mixes, icings, and fillings, and in the frying of foods	1 percent when used alone. If used with polysorbate 60 the combined total shall not exceed 1 percent
	Propylene glycol mono and diesters of fats and fatty acids	do	Rendered animal fat or a combination of such fat with vegetable fat	Sufficient for purpose
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate)	do	Shortening for use in nonstandardized baked goods, baking mixes, icings, and fillings, and in the frying of foods	1 percent when used alone. If used with polysorbate 80 the combined total shall not exceed 1 percent
	Stearyl-2 lactylic acid	do	Shortening to be used for cake icings and fillings	3.0 percent
	Stearyl monoglyceridyl citrate	do	Shortening	Sufficient for purpose
Flavoring agents; protectors and developers	Program approved artificial smoke flavoring	To flavor product	Various	Do
	Program approved smoke flavoring	do	do	Do
	Autolyzed yeast extract	do	do	Do

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
Flavoring agents, protectors and developers.	Harmless bacteria starters of the acidophilus type, lactic acid starter or culture of *Pediococcus cerevisiae*	To develop flavor	Dry sausage, pork roll, thuringer, lebanon bologna, cervelat, and salami	0.5 percent
	do	To dissipate nitrite	Bacon	Sufficient for purpose
	Benzoic acid, sodium benzoate.	To retard flavor reversion	Oleomargarine	0.1 percent
	Citric acid	To protect flavor	do	Sufficient for purpose
	do	Flavoring	Chili con carne	Do.
	Corn syrup solids, corn syrup, glucose syrup	To flavor	Sausage, hamburger, meat loaf, luncheon meat, chopped or pressed ham	2.0 percent individually or collectively, calculated on a dry basis.
	Dextrose	To flavor product.	Sausage, ham and cured products	Sufficient for purpose
	Diacetyl	do	Oleomargarine	Do
	Disodium guanylate	do	Various [1]	Do
	Disodium inosinate	do	do	Do
	Hydrolyzed plant protein	do	do	Do
	Isopropyl citrate	To protect flavor	Oleomargarine	0.02 percent
	Malt syrup	To flavor product.	Cured products	2.5 percent
	Milk protein hydrolysate	do	Various [1]	Sufficient for purpose
	Monosodium glutamate	do	do	Do
	Sodium sulfoacetate derivative of mono and diglycerides.	do	do	0.5 percent
	Sodium tripolyphosphate	To help protect flavor	"Fresh Beef," "Beef for Further Cooking," "Cooked Beef," and similar products which are frozen after processing.	Do
	Mixtures of sodium tripolyphosphate and sodium hexametaphosphate	do	do	Do
	Sorbitol	To flavor, to facilitate the removal of casings from product and to reduce caramelization and charring.	Cooked sausage labeled frankfurter, frank, furter, wiener, knockwurst	Not more than 2 percent of the weight of the formula, excluding the formula weight of water or ice, not permitted in combination with corn syrup, and/or corn syrup solids
	Starter distillate	To help protect flavor	Oleomargarine	Sufficient for purpose
	Stearyl citrate	To protect flavor	do	0.15 percent
	Sugars (sucrose and dextrose)	To flavor product	Various [1]	Sufficient for purpose
Gases	Carbon dioxide solid (dry ice)	To cool product	Chopping of meat, packaging of product.	Do
	Nitrogen	To exclude oxygen	Sealed container	Do
Hog scald agents (must be removed by subsequent cleaning operations)	Caustic soda	To remove hair	Hog carcasses	Do
	Dioctyl sodium sulfosuccinate	do	do	Do
	Lime	do	do	Do
	Methyl polysilicone	do	do	Do
	Sodium carbonate	do	do	Do
	Sodium dodecylbenzene sulfonate	do	do	Do
	Sodium hexametaphosphate	do	do	Do
	Sodium lauryl sulfate	do	do	Do

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
Refining agents (must be eliminated during process of manufacturing).	Acetic acid	To seperate fatty acids and glycerol.	Rendered fats	Sufficient for purpose.
	Bicarbonate of soda	do	do	Do
	Carbon (purified charcoal).	To aid in refining of animal fats.	do	Do
	Caustic soda (sodium hydroxide)	To refine fats	do	Do
	Diatomaceous earth, Fuller's earth	do	do	Do.
	Sodium carbonate	do	do	Do
	Tannic acid	do	do	Do
Rendering agents	Tricalcium phosphate	To aid rendering	Animal fats	Do
	Trisodium phosphate	do	do	Do
Artificial sweetners	Saccharin	To sweeten product	Bacon	0.01 percent.
Synergists (used in combination with antioxidants).	Citric acid	To increase effectiveness of antioxidants.	Lard and shortening	0.01 percent alone or in combination with antioxidants in lard or shortening
	do	do	Dry sausage	0.003 percent in dry sausage in combination with antioxidants.
	do	do	Fresh pork sausage	0.01 percent on basis of fat content, in combination with antioxidants.
	do	do	Dried meats	0.01 percent on basis of total weight in combination with antioxidants.
	Malic acid	do	Lard and shortening.	Do
	Monoisopropyl citrate	do	Lard, shortening, oleomargarine, fresh pork sausage, dried meats.	0.02 percent.
	Phosphoric acid	do	Lard and shortening	0.01 percent
	Monoglyceride citrate	do	Lard, shortening, fresh pork sausage, dried meats.	0.02 percent.

EXHIBIT 4-1 (Continued)

FOOD SUBSTANCES: MEAT PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
Hog scald agents, must be removed by subsequent cleaning operations.	Sodium metasilicate	To remove hair	Hog carcasses	Sufficient for purpose
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} to C_{16}).	do	do	Do.
	Sodium sulfate	do	do	Do.
	Sodium tripolyphosphate	do	do	Do.
	Sucrose	do	do	Do.
	Trisodium phosphate	do	do	Do.
Miscellaneous	Potassium sorbate	To retard mold growth.	Dry sausage	2.5 percent in water solution may be applied to casings after stuffing or casings may be dipped in solution prior to stuffing.
	do	To preserve product and to retard mold growth.	Oleomargarine or margarine.	0.1 percent by weight of the finished oleomargarine or margarine.
	Calcium disodium, EDTA (calcium disodium ethylenediaminetetraacetate).	To preserve product and to protect flavor.	do	75 parts per million by weight of the finished oleomargarine or margarine.
	Propyl paraben (propyl p-hydroxybenzoate).	To retard mold growth	Dry sausage	3.5 percent in water solution may be applied to casings after stuffing, or casings may be dipped in solution prior to stuffing.
	Sodium bicarbonate	To neutralize excess acidity, cleaning vegetables.	Rendered fats, soups, curing pickle.	Sufficient for purpose.
	Calcium propionate	To retard mold growth.	Pizza crust	0.32 percent alone or in combination based on weight of the flour brace used.
	Sodium propionate	do	do	Do.
	Sodium hydroxide	To decrease amount of cooked out juices.	Cured hams, pork shoulder picnics and loins, canned hams and pork shoulder picnics, and products covered by § 319.104(d); chopped ham and bacon.	May be used only in combination with phosphates in ratio of four parts phosphate to one part sodium hydroxide; the combination shall not exceed 5 percent in pickle at 10 percent pump level; 0.5 percent in product.
Phosphates	Disodium phosphate	do	do	5 percent of phosphate in pickle at 10 percent pump level; 0.5 percent of phosphate in product (only clear solution may be injected into product).
	Monosodium phosphate	do	do	Do.
	Sodium hexametaphosphate.	do	do	Do.
	Sodium tripolyphosphate	do	do	Do.
	Sodium pyrophosphate	do	do	Do.
	Sodium acid pyrophosphate	do	do	Do.
Proteolytic enzymes	Aspergillus oryzae	To soften tissues	Beef cuts	Solutions consisting of water, salt, monosodium glutamate, and approved proteolytic enzymes applied or injected into cuts of beef shall not result in a gain of more than 3 percent above the weight of the untreated product.
	Aspergillus flavus-oryzae group	do	do	Do.
	Bromelin	do	do	Do.
	Ficin	do	do	Do.
Papain		do	do	Do.

EXHIBIT 4-2

FOOD SUBSTANCES: POULTRY PRODUCTS b/

Class of substance	Substance	Purpose	Products	Amount
Antifoaming agent	Methyl polysilicone	To retard foaming	Soups	10 ppm.
			Rendered fats	10 ppm.
			Curing pickle	50 ppm.
Antioxidants and oxygen interceptors	BHA (butylated hydroxyanisole)	To retard rancidity	Various	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant listed in this table based on fat content.)
	BHT (butylated hydroxytoluene)	do	do	Do.
	Propyl gallate	do	do	0.01 percent based on fat content (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
	TBHQ (tertiary butylhydroquinone)	do	do	0.01 percent based on fat content (0.02 percent in combination only with BHA and/or BHT based on fat content.)
	Tocopherols	do	do	0.03 percent based on fat content (0.02 percent in combination with any other antioxidant listed in this table, except TBHQ, based on fat content.)
Binders and extenders	Algin	To extend and stabilize product	do	Sufficient for purpose.
	Carrageenan	do	do	Do.
	Carboxymethyl cellulose (cellulose gum).	do	do	Do.
	Gums, vegetable	do	do	Do.
	Methyl cellulose	To extend and to stabilize product (also carrier).	do	0.15 percent.
	Isolated soy protein	To bind and extend product	do	Sufficient for purpose.
	Sodium caseinate	do	do	Do.
	Whey (dried)	do	do	Do.
	Xanthan gum	To maintain: Uniform viscosity; suspension of particulate matter; emulsion stability; freeze-thaw stability.	Various, except uncooked products or sausages or other products with a moisture limitation established by Subpart P of this Part.	Do.
Chilling media	Salt (NaCl)	To aid in chilling	Raw poultry products	700 lbs. to 10,000 gals. of water.¹
Coloring agents (natural)	Annatto, Carotene	To color products	Various	Sufficient for purpose.
Coloring agents (artificial)	Coal tar dyes (FD&C certified).	To color products	do	Do.
	Titanium dioxide.	to whiten products.	Salads and spreads	0.05 percent.
Cooking and retort water treatment agents.	Calcium chloride	To prevent staining on exterior or canned goods.	Various	Sufficient for purpose.
	Citric acid	do	do	Do.
	Dioctyl sodium sulfosuccinate	do	do	0.05 percent.
	Disodium calcium ethylenediamine-tetraacetate	do	do	Sufficient for purpose.
	Disodium ethylenediamine-tetraacetate.	do	do	Do.
	Disodium phosphate	do	do	Do
	Ethylenediamine tetraacetic acid	do	do	Do

b/9 CFR 381.147

EXHIBIT 4-2 (Continued)

FOOD SUBSTANCES: POULTRY PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
		To prevent staining on exterior or canned goods		
	Isopropanol	do	Various	0.002 percent.
	Potassium pyrophosphate	do	do	Sufficient for purpose.
	Propylane glycol	do	do	Do.
	Sodium bicarbonate	do	do	Do.
	Sodium carbonate	do	do	Do.
	Sodium dodecylbenzene sulfonate.	do	do	0.05 percent.
	Sodium gluconate	do	do	Sufficient for purpose.
	Sodium hexametaphosphate	do	do	Do.
	Sodium laurylsulfate	do	do	0.05 percent.
	Sodium metasilicate	do	do	Sufficient for purpose.
	Sodium n-alkylbenzene sulfonate (alkyl group predominantly C_{12} and C_{13} and not less than 95 percent C_{10} to C_{16})	do	do	0.05 percent.
	Sodium nitrite (The sodium nitrite must be decharacterized with 0.05 percent powdered charcoal. Bulk decharacterized sodium nitrite when in cook room shall be held in locked metal bin or container conspicuously labeled "Decharacterized sodium nitrite—To be used by authorized personnal only.").	To inhibit corrosion on exterior of canned goods.	do	800 parts per million.
	Sodium pyrophosphate	To prevent staining on canned goods.	do	0.05 percent.
	Sodium tripolyphosphate	do	do	Do.
	Zinc oxide	do	do	0.01 percent.
	Zinc sulfate	do	do	Do.
Curing accelerators; must be used only in combination with curing agents.	Ascorbic acid	To accelerate color fixing	Cured poultry; cured, comminuted poultry products	75 oz to 100 gal pickle at 10 percent pump level; ¾ oz to 100 lb of poultry product; 10 percent solution to surfaces of the product prior to packaging (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)
	Erythorbic acid	do	do	Do.
	Sodium ascorbate	do	do	87.5 oz to 100 gal pickle at 10 percent pump level; ⅞ oz to 100 lb of poultry product; 10 percent solution to surfaces of product prior to packaging (The use of such solution shall not result in the addition of a significant amount of moisture to the product.)

EXHIBIT 4-2 (Continued)

FOOD SUBSTANCES: POULTRY PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
	Sodium erythorbate	do	do	Do
	Citric acid or sodium citrate	do	do	May be used in cured products to replace up to 50 percent of the ascorbic acid or sodium erythorbate that is used
Curing agents	Sodium or potassium nitrate	Source of nitrite	do	7 lb to 100 gal pickle; 3½ oz. to 100 lb of poultry product (dry cure); 2¾ oz to 100 lb of chopped poultry meat
	Sodium or potassium nitrite (Supplies of sodium nitrite and potassium nitrite and mixtures containing them must be kept securely under the care of a responsible employee of the establishment. The specific nitrite content of such supplies must be known and clearly marked accordingly).	To fix color	Cured products	2 lb to 100 gal pickle at 10 percent pump level; 1 oz to 100 lb of poultry product (dry cure); ¼ oz to 100 lb chopped poultry meat. The use of nitrites, nitrates, or combination shall not result in more than 200 ppm of nitrite, calculated as sodium nitrite, in finished product.
Emulsifying agents	Acetylated monoglycerides	To emulsify product	Various	Sufficient for purpose.
	Diacetyl tartaric acid esters of mono- and diglycerides.	do	Rendered poultry fat or a combination of such fat with vegetable fat	Do.
	Glycerol-lacto stearate, oleate or palmitate	do	do	Do.
	Lecithin	To emulsify product (also as antioxidant).	Various	Do
	Mono- and diglycerides (glycerol palmitate, etc.)	To emulsify product	do	Do
	Polysorbate 80 (polyoxyethylene (20) sorbitan monooleate).	do	do	1 percent when used alone. If used with polysorbate 60, the combined total shall not exceed 1 percent.
	Propylene glycol mono- and diesters of fats and fatty acids.	do	Rendered poultry fat or a combination of such fat with vegetable fat.	Sufficient for purpose
	Polysorbate 60 (polyoxyethylene (20) sorbitan monostearate)	do	do	1 percent when used alone. If used with polysorbate 80, the combined total shall not exceed 1 percent.
Flavoring agents, protectors and developers	Approved artificial smoke flavorings [3]	To flavor product	Various	Sufficient for purpose
	Approved smoke flavoring [3]	do	do	Do
	Autolyzed yeast extract	do	do	Do
	Citric acid	To protect flavor	do	Do

EXHIBIT 4-2 (Continued)

FOOD SUBSTANCES: POULTRY PRODUCTS

Class of substance	Substance	Purpose	Products	Amount
	Corn syrup solids; corn syrup; glucose syrup	To flavor product	Various	Sufficient for purpose
	Disodium inosinate	do	do	Do.
	Disodium guanylate	do	do	Do.
	Hydrolyzed plant protein	do	do	Do.
	Malt syrup	do	do	Do.
	Milk protein hydrolysate	do	do	Do.
	Monosodium glutamate	do	do	Do.
	Sodium sulfoacetate derivative of mono and diglycerides.	do	do	0.5 percent.
	Sugars approved (sucrose and dextrose).	do	do	Sufficient for purpose.
Gases	Carbon dioxide solid (dry ice)	To cool product or facilitate chopping or packaging.	Various	Do.
	Carbon dioxide liquid	Contact freezing	do	Do.
	Nitrogen	To exclude oxygen from sealed containers.	do	Do.
	Nitrogen liquid	Contact freezing	do	Do.
Miscellaneous	Sodium bicarbonate	To neutralize excess acidity; cleaning vegetables.	Rendered fat, soups, curing pickle.	Do.
	Calcium propionate	To retard mold growth	Fresh pie dough	0.3 percent of calcium propionate or sodium propionate alone, or in combination, based on weight of the flour used.
	Sodium propionate	do	do	Do.
Phosphates	Disodium phosphate	To decrease the amount of cooked out juices and protect flavor.	Various	0.5 percent in product.
	Monosodium phosphate	do	do	Do.
	Sodium hexametaphosphate	do	do	Do.
	Sodium tripolyphosphate	do	do	Do.
	Sodium pyrophosphate	do	do	Do.
	Sodium acid pyrophosphate	do	do	Do.
Synergists (used in combination with antioxidants)	Citric acid	To increase effectiveness of antioxidants.	Poultry fats	0.01 percent alone or in combination with antioxidants in poultry fats.
	Malic acid	do	do	Do.
	Monoisopropyl citrate	do	do	0.01 percent poultry fats.
	Phosphoric acid	do	do	0.01 percent.
	Monoglyceride citrate	do	do	0.02 percent.

CONSUMER PRODUCT SAFETY COMMISSION

The Consumer Product Safety Commission is responsible for the implementation of three Acts of Congress concerning hazardous chemicals:

- Federal Hazardous Substances Act,
- Poison Prevention Packaging Act.
- Flammable Fabrics Act, and
- Consumer Product Safety Act.

The statutory and regulatory reviews that follow do not necessarily represent the official position of the Commission and have not been reviewed or approved by the Commission. Moreover, this material has not been officialy endorsed by the EPA as it understanding of CPSC authority. The contractor ICF Incorporated is solely responsible for all analyses and interpretations.

FEDERAL HAZARDOUS SUBSTANCES ACT--
STATUTORY REVIEW

BACKGROUND

By 1960, advances in the field of applied chemistry had resulted in a proliferation of new and useful household aid products which, while quite beneficial overall, had outstripped the ability of existing regulations to help prevent harm resulting from their use.[1] The Federal Caustic Poison Act had been enacted in 1927[2] and required informative labeling of only a fraction of the potentially deadly chemicals then on the market. Similarly, the labeling requirements of the Federal Food, Drug, and Cosmetic Act (FDCA)[3] and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[4] were not sufficiently broad to adequately protect the public.[5] These facts, together with the estimated 500 deaths annually resulting from 600,000 incidents of children swallowing household aids and the additional death and injury to adults from household substances not bearing cautionary labels, prompted the passage of the Federal Hazardous Substances Labeling Act in 1960.[6]

The House Committee on Interstate and Foreign Commerce Report stated the purpose of the Act as follows:

> The purpose of this bill is to provide nationally uniform requirements for adequate cautionary labeling of packages of hazardous substances which are sold in interstate commerce and are intended or suitable for household use.
>
> The labeling requirements will advise the user of these hazardous substances in the use of the product and make available immediate information for physicians who are called upon to treat cases of accidental injury. It should also provide a pattern which States may follow in enacting similar legislation.[7]

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[1] H.R. Rep. No. 1861, 86th Cong., 2nd Sess., *reprinted in* U.S. Code Cong. and Ad. News 2833, 2834 (1960) (hereafter cited as House Report).

[2] 15 USC 401-411 (partially repealed by the Federal Hazardous Substances Act and its 1969 amendment).

[3] 21 USC 301 *et seq.*

[4] 7 USC 136 *et seq.*

[5] House Report at 2834.

[6] *Ibid.*

[7] House Report at 2833.

The original Act was, as its name implies, mainly a labeling act. It was, however, subsequently broadened. In 1966, the Act was amended[8] to allow the banning of toys and other children's articles as well as certain substances which are so hazardous in nature that even proper labeling cannot make them safe for household use. The purpose of this amendment was:

> [T]o ban the sale of toys and other children's articles containing hazardous substances; to authorize the Secretary of Health, Education, and Welfare to ban the sale of other substances which are so hazardous in nature that they cannot be made suitable for use in or around the household by cautionary labeling; to extend coverage of the Hazardous Substances Labeling Act to unpackaged as well as packaged hazardous substances intended for household use; and to make it clear that household products treated with pesticides are not exempt from that act.[9]

The name of the Act was changed to the Federal Hazardous Substances Act (FHSA), its present title, to reflect this wider scope.

The Act was again amended in 1969 to cover electrical, mechanical, and thermal hazards posed by toys and other children's articles.[10] The functions of the Secretary of Health, Education, and Welfare under FHSA were transferred to the Consumer Product Safety Commission (the Commission) in 1972.[11]

This statutory review of FHSA will deal mainly with the definition of "hazardous substance," "misbranded hazardous substance," and "banned hazardous substance." Through a discussion of each of these terms, the workings of FHSA will be revealed.

SUBSTANCES COVERED AND STATUTORY CRITERIA

FHSA defines "hazardous substance" as:

> (1) (A) any substance or mixture of substances which (i) is toxic, (ii) is corrosive, (iii) is an irritant, (iv) is a strong sensitizer, (v) is flammable or combustible, or (vi) generates pressure through decomposition,

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[8] Child Protection Act of 1966, Pub. L. No. 89-756, 80 Stat. 1303, 1304, 1305.

[9] H.R. Rep. No. 2166, 89th Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 4095 (1966).

[10] Child Protection Act of 1969, Pub. L. No. 91-113, 83 Stat. 187-189.

[11] 15 USC 2079(a).

> heat, or other means, if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
>
> (B) Any substances which the Secretary by regulation finds, . . . meet the requirements of subparagraph (1)(A) of this paragraph.
>
> (C) Any radioactive substance, if, with respect to such substance as used in a particular class of article or as packaged, the Secretary determines by regulation that the substance is sufficiently hazardous to require labeling in accordance with this chapter in order to protect the public health.
>
> (D) Any toy or other article intended for use by children which the Secretary by regulation determines, ...presents an electrical, mechanical, or thermal[12] hazard.[13]

The categories specified in this definition are carefully defined in FHSA. Exhibit 5-1 lists the definitions of the categories mentioned in §1261(f)(1)(A), while Exhibit 5-2 lists some of the definitions used in §1261(f)(1)(B)-(D) and elsewhere in the Act. Exemptions from this definition of "hazardous substance" for certain substances covered by other statutes are given in §1261(b)(2) and §1261(b)(3):

> (2) The term 'hazardous substance' shall not apply to pesticides subject to the Federal Insecticide, Fungicide, and Rodenticide Act, nor to foods, drugs and cosmetics subject to the Federal Food, Drug, and Cosmetic Act, nor to substances intended for use as fuels when stored in containers and used in the heating, cooking, or refrigeration system of a house, nor to tobacco and tobacco products, but such terms shall apply to any article which is not itself a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act but which is a hazardous substance within the meaning of paragraph (1) of this subsection by reason of bearing or containing such a pesticide.

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[12] See Exhibit 5-2 for definitions of "electrical," "mechanical," and "thermal" hazards.

[13] 15 USC 1261(f)(1).

EXHIBIT 5-1

DEFINITIONS OF TERMS USED IN 15 USC 1261(f)(1)(A)

Term	Definition and Section
Toxic	Shall apply to any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface. §1261(g).
Corrosive	Any substance which in contact with living tissue will cause destruction of tissue by chemical action; but shall not refer to action on inanimate surfaces. §1261(i).
Irritant	Any substance not corrosive within the meaning of subparagraph (i) of this section which on immediate, prolonged, or repeated contact with normal living tissue will induce a local inflammatory reaction. §1261(j).
Strong Sensitizer	A substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated as such by the Secretary. Before designating any substance as a strong sensitizer, the Secretary, upon consideration of the frequency of occurrence and severity of the reaction, shall find that the substance has a significant potential for causing hypersensitivity. §1261(k).
Flammable	Shall be defined by regulations issued by the Commission. §1261(l).
Combustible	Shall be defined by regulations issued by the Commission.* §1261(l).

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* 15 USC §1261(l)(4) provides: "Until such time as the Commission issues a regulation . . . defining the term "combustible" as applied to liquids, such term shall apply to any liquid which has a flash point above eighty degrees Fahrenheit [up] to and including one hundred and fifty degrees, as determined by the Tagliabue Open Cup Tester."

EXHIBIT 5-2

DEFINITIONS OF OTHER TERMS USED IN FHSA

Term	Definition and Section
Highly Toxic	(1) Any substance which falls within any of the following categories: (a) Produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, at a single dose of fifty milligrams or less per kilogram of body weight, when orally administered; or (b) produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two hundred and three hundred grams, when inhaled continuously for a period of one hour or less at an atmospheric concentration of two hundred parts per million by volume or less of gas or vapor or two milligrams per liter by volume or less of mist or dust, provided such concentration is likely to be encountered by man when the substance is used in any reasonably foreseeable manner; or (c) produces death within fourteen days in half or more than half of a group of ten or more rabbits tested in a dosage of two hundred milligrams or less per kilogram of body weight, when administered by continuous contact with the bare skin for twenty-four hours or less. (2) If the Secretary finds that available data on human experience with any substance indicate results different from those obtained on animals in the above-named dosages or concentrations, the human data shall take precedence. §1261(h).

EXHIBIT 5-2

DEFINITIONS OF OTHER TERMS USED IN FHSA
(Continued)

Term	Definition and Section
Extremely Flammable	Shall be defined by regulations issued by the Commission. §1261(l).
Radioactive Substance	A substance which emits ionizing radiation. §1261(m).
Electrical Hazard	An article may be determined to present an electrical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture may cause personal injury or illness by electric shock. §1261(r).
Mechanical Hazard	An article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness (1) from fracture, fragmentation, or disassembly of the article, (2) from propulsion of the article (or any part or accessory thereof), (3) from points or other protrusions, surfaces, edges, openings, or closures, (4) from moving parts, (5) from lack or insufficiency of controls to reduce or stop motion, (6) as a result of self-adhering characteristics of the article, (7) because the article (or any part or accessory thereof) may be aspirated or ingested, (8) because of instability, or (9) because of any other aspect of the article's design or manufacture. §1261(s).

EXHIBIT 5-2

DEFINITIONS OF OTHER TERMS USED IN FHSA
(Continued)

Term	Definition and Section
Thermal Hazard	An article may be determined to present a thermal hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness because of heat as from heated parts, substances, or surfaces. §1261(t).

> (3) The term 'hazardous substance' shall not include any source material, special nuclear material, or byproduct material as defined in the Atomic Energy Act of 1954, as amended, and regulations issued pursuant thereto by the Atomic Energy Commission.

Ther are thus two basic ways that a substance is deemed hazardous under FHSA. One is that under 15 USC 1261(f)(1)(B), (C), and (D), the Commission may designate, by regulation, certain substances as hazardous. The other is by the terms of the statute itself, 15 USC 1261(f)(1)(A). The House Report discussed the key elements of this latter provision:

> In order to come within the basic definition of 'hazardous substance,' a substance (or mixture) must meet two requirements. First, it must be 'toxic,' 'corrosive,' an 'irritant,' a 'strong sensitizer' designated by the Secretary, 'flammable,' or be a substance which 'generates pressure through decomposition, heat, or other means.' (All these terms, except the self-explanatory phrase 'generates pressure through decomposition, heat, or other means,' are defined in the bill). Secondly, it must be a substance (or mixture) which--
>
>> may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children.
>
> The term 'substantial,' in the expression 'substantial personal injury or substantial illness,' should be read in the light of the purposes of the bill. On the one hand, it is not intended to impose the impracticable and self-defeating requirement of cautionary labeling against wholly insignificant or negligible illness or injury, such as the very temporary indisposition that a child might suffer from eating a piece of the standard type of toilet soap. The committee recognizes that virtually every substance used in or about the household is capable of causing some degree of illness or injury if accidentally or intentionally misused. If labeling were required to caution against the risk of even the most trifling indisposition, there would hardly be any substance going into the household which would not have to bear cautionary labeling, so that consumers would tend more and more to disregard label warnings, thus inviting indifference to cautionary statements on packages of substances presenting a real hazard of substantial injury or illness. On the other hand, the term 'substantial' is not intended to limit the requirement of cautionary labeling to situations in which the injury or illness to be guarded against would be severe or serious.

> Further, as above noted, the bill requires that there be a risk of the occurrence of injury or illness' during or as a proximate result of any customary or reasonably foreseeable handling or use' of the package or substance. This phrase, again, is intended to be read in the light of the purpose of the bill. This purpose includes customary or reasonably foreseeable accidental handling or use, not only by the purchaser or intended user of the product, but by others in the household, especially children who are prone to swallow or tamper with household aids left within their reach. It is common knowledge that the very color and attractive modern packaging of a poisonous household substance, such as furniture or silver polish, may induce a small child to investigate and to swallow it.[14]

The Senate Report echoed many of the points made above by the House Report, and added:

> It is intended by the definition of a hazardous substance to bring within the scope of this bill those substances which, as packaged, may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use. This includes ingestion by children whenever such is reasonably foreseeable (and the bill recognizes that it is often reasonably foreseeable). It is also intended by these definitions to draw as clear a line of distinction as possible between the substances covered by this bill and the substances which are unaffected by its employing the language of the common law of civil liability in drawing such a line. In order to insure that the definitions will include all substances which should be within the scope of the bill, these definitions are broad in scope. They are not intended, however, to include substances where the hazard is minor taking into account on the one hand the risk or chance of injury and on the other hand the degree of injury probable or possible in case of accidental or intentional misuse.[15]

The definition of hazardous substance in FHSA operates mainly through the rubrics 'misbranded hazardous substance' and 'banned hazardous substance', both of which are prohibited from interstate commerce by 15 USC 1263. 'Misbranded hazardous substance' is basically defined as:

> [A] hazardous substance (including a toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in

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[14] House Report at 2837.

[15] S. Rep. No. 1158, 86th Cong., 2nd Sess. 10-11 (1960).

such manner as to be susceptible of access by a child to whom such toy or other article is entrusted) intended, or packaged in a form suitable, for use in the household or by children, if the packaging or labeling of such substance is in violation of an applicable regulation. . . or if such substance, except as otherwise provided . . ., fails to bear a label--

> (1) which states conspicuously (A) the name and place of business of the manufacturer, packer, distributor or seller; (B) the common or usual name or the chemical name (if there be no common or usual name) of the hazardous substance or of each component which contributes substantially to its hazard, unless the Secretary by regulation permits or requires the use of a recognized generic name; (C) the signal word 'DANGER' on substances which are extremely flammable;[16] corrosive,[17] or highly toxic;[18] (D) the signal word 'WARNING' or 'CAUTION' on all other hazardous substances; (E) an affirmatiave statement of the principal hazard or hazards, such as 'Flammable', 'Combustible', 'Vapor Harmful', 'Causes Burns', 'Absorbed Through Skin', or similar wording descriptive of the hazard; (F) precautionary measures describing the action to be followed or avoided, except when modified by regulation of the Secretary...; (G) instruction, when necessary or appropriate, for first-aid treatment; (H) the word 'poison' for any hazardous substance which is defined as 'highly toxic' by subsection (h) of this section; (I) instructions for handling and storage of packages which require special care in handling or storage; and (J) the statement (i) 'Keep out of the reach of children' or its practical equivalent, or, (ii) if the article is intended for use by children and is not a banned hazardous substance, adequate directions for the protection of children from the hazard, and

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[16] See Exhibit 5-2 for statutory statement concerning "extremely flammable."

[17] See Exhibit 5-1 for definition of "corrosive."

[18] See Exhibit 5-2 for definition of "highly toxic."

> (2) on which any statements required under subparagraph (1) of this paragraph are located prominently and are in the English language in conspicuous and legible type in contrast to typography, layout, or color with other printed matter on the label.[19]

"Banned hazardous substance" is defined by 15 USC 1261(q)(1):

> The term 'banned hazardous substance' means (A) any toy, or other article intended for use by children, which is a hazardous substance, or which bears or contains a hazardous substance in such manner as to be susceptible of access by a child to whom such toy or other article is entrusted; or (B) any hazardous substance intended, or packaged in a form suitable, for use in the household, which the Secretary by regulation classifies as a 'banned hazardous substance' on the basis of a finding that, notwithstanding such cautionary labeling as is or may be required under this chapter for that substance, the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce.[20]

These two definitions are particularly important because 15 USC 1263 prohibits the introduction into, delivery for introduction into, or the receipt in interstate commerce of either category of substance.[21] Interstate commerce has been interpreted rather broadly. One case, for example, has held that Congress, under its power to regulate interstate commerce, may even regulate wheat consumed on the farm where it is grown (that is, wheat that is never sold to anyone).[22] With respect to FHSA, interstate shipment has been held to be proven if the evidence shows that the product in issue was found in the state but manufactured elsewhere (in other words, direct proof of the shipment is not necessary).[23]

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[19] 15 USC 1261(p). This definition also includes certain improperly labeled or packaged household substances covered by the Poison Prevention Packaging Act of 1970, 15 USC 1471(2)(D). See also the Statutory Review of that Act.

[20] Such items as chemistry sets and common fireworks may be exempted (by regulation) from clause (A).

[21] This section also prohibits the adulteration of labels of hazardous substances and certain other acts.

[22] Wickard v. Filburn, 317 U.S. 11 (1942).

[23] U.S. v. Chalaire, 316 F. Supp. 543 (D.C. La. 1970).

Several other cases have interpreted the coverage of FHSA. In Barnes v. Litton Industrial Products, Inc.,[24] the court held that while burning alcohol falls within the definition of "hazardous substance" under FHSA,[25] it did not require labeling as a hazardous substance under the Act because it was not regularly purchased by consumers for household use. Another case, United States v. 7 Cases, Cracker Balls,[26] found that cracker balls are a hazardous substance, and are subject to FHSA labeling requirements. Two other cases found FHSA applicable to the substances involved.[27]

Probably the leading case on FHSA is Forester v. Consumer Product Safety Commission,[28] in which regulations establishing standards for the manufacture and labeling of most bicycles were challenged. The first set of issues discussed by the court involved whether the powers of the Commission under FHSA included the power to establish design, as well as performance, standards. The court held that it did have such power and, in addition, that it also had "the power to make distinctions between products within a single class."[29]

The court next addressed the issue of how the Commission may regulate items which are capable of use by both adults and children. The hazardous substance definition of 15 USC §1261(F)(1)(D) dealing with electrical, thermal, and mechanical hazards covers only toys or other articles "intended for use by children," but bicycles are clearly used by adults also. The court stated:

> The language and intent of the FHSA turn upon intended use... [T]he relevant intent is like that in tort law -- a result is intended if it is a reasonably foreseeable result of one's actions. Incidental use of an item by adults would not deprive the Commission of jurisdiction to regulate the item under the FHSA, and incidental use by children would not create such jursidiction.

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[24] 555 F.2d 1184 (4th Cir. 1977).

[25] 15 USC 1261(f).

[26] 253 F. Supp. 771 (D.C. Tex. 1966).

[27] United States v. Chalaire, 316 F. Supp. 543 (D.C. La. 1970) (silver-kings and cherry bombs); R.B. Jarts, Inc. v. Richardson, 438 F.2d 846 (2nd Cir. 1971) (lawn dart game).

[28] 559 F.2d 774 (D.C. Cir. 1977).

[29] 559 F.2d at 782.

> Determination of such 'intent,' however, is vested in the sound discretion of the Commission. This is particularly so '[b]etween the [ ] [sic] ends of the spectrum,' where ...full-sized bicycles fall. In view of the evidence considered by the Commission in this case, we cannot conclude that it abused its discretion or acted contrary to law in determining that all bicycles except those excluded from the regulations are 'intended for use by children.'[30]

The next issue in front of the District of Columbia Court of Appeals was the question of whether the power of the Commission under FHSA was limited to establishing labeling requirements for "bicycles intended for use by adults and children of sufficient maturity to understand and heed the instructions."[31]

> We conclude that the Commission is free in its sound discretion to adopt design and performance requirements dealing with hazards that are susceptible to elimination by these means. The precise outline of the proviso must be determined only (1) where the design or performance regulations would seriously compromise the function of the article regulated, or (2) where the Commission seeks to ban a product outright rather than permitting its sale with warnings. The Commission has not sought to ban bicycles outright. A determination that the regulations issued do not seriously compromise the function of bicycles underlies the decision to promulgate the regulations... For the present, we find that it is not contrary to law for the Commission to rely in part upon design and performance requirements affecting bicycles for persons of sufficient maturity to understand and follow instructions.[32]

The other major issue considered by the court was the level of risk which the Commission is required to find before the Commission is empowered to act.[33] This question arose in the context of whether an article poses a mechanical risk. Such risk exists only when "an unreasonable risk of personal injury or illness" is presented.[34] The court concluded:

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[30] Emphasis in original. Footnote omitted. 559 F.2d at 786.

[31] 559 F.2d at 786.

[32] 559 F.2d at 787.

[33] The issue of unreasonableness of risk was also addressed in Clever Idea Company v. Consumer Product Safety Commission, 385 F. Supp. 688 (E.D.N.Y. 1974). There, the Commission failed to prove that the risk of injury from plastic toy mouthpieces was unreasonable.

[34] 15 USC 1261(s).

> There is no indication in the language of the Act or its legislative history that the Commission was bound to develop a precise 'body count' of actual injuries that will be reduced by each regulatory provision... We conclude that no precise statistical showing is required.
>
> The Commission is, however, permitted by the FHSA to regulate only mechanical hazards that present 'an unreasonable risk' of consumer injury. This means that the Commission must determine (1) that the risk posed by the hazard is an unreasonable one, and (2) that there is a sufficient nexus between the regulation and the hazard it is designed to prevent. The requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.[35]

In support of this last point, the court cited the legislative history, a portion of which provided, "Before the Secretary banned such items he would consider such factors as the utility of the object, the degree of danger it presents, and the feasibility of designing out that danger."[36] Balancing tests such as that suggested here are common in the law.[37]

Note, however, that the reasoning of the court may not be applicable to all hazardous substances under FHSA. Only children's articles posing mechanical and thermal hazards under the statute are based on the notion of an "unreasonable risk" of injury or illness, on which the court placed its emphasis here. Other FHSA provisions do not incorporate this concept and so are not necessarily subject to the court's analysis of this issue.

Returning again to the statute itself, FHSA provides criminal penalties for violating 15 USC 1263,[38] allows for seizure of misbranded or banned hazardous substances,[39] and gives the Commission other powers necessary to carry out the Act.[40]

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[35] Footnote omitted. 559 F.2d at 788-789.

[36] 559 F.2d at 789 n.21, quoting from S. Rep. No. 91-237, 91st Cong., 1st Sess. 7 (1969).

[37] *See*, *for example*, the Statutory Review of the Consumer Product Safety Act.

[38] 15 USC 1264.

[39] 15 USC 1265.

[40] *E.g.*, 15 USC 1262 (power to promulgate regulations and make exemptions); 15 USC 1270 (examinations and investigations); 15 USC 1271 (access to records).

In addition, FHSA states that, in general, if the Commission has adopted a regulation relating to a hazardous substance under this Act, then no state or local government may establish or continue in effect a regulation designed to protect against the same risk of illness or injury unless it is identical to the federal regulation.[41] In certain circumstances, however, a stricter state or local regulation is permissible.[42]

SUMMARY

FHSA prohibits the entry into interstate commerce of substances which are improperly labeled ("misbranded hazardous substances") or banned because of the hazards they pose to children or to adults despite proper labeling ("banned hazardous substances"). The definitions of these phrases are based on the Act's definition of "hazardous substance," which is therefore of central importance. A substance is hazardous either as a result of regulation under the Act or because it is in one of the categories listed in Exhibit 5-1 and poses the required risk of substantial personal injury or substantial illness.

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[41] See 15 USCA 1261 note; Pub. L. No. 86-613, §18, formerly 17, July 12, 1960, 74 Stat. 380, as amended Pub. L. No. 89-756, §4(a), Nov. 3, 1966, 80 Stat. 1305; renumbered and amended Pub. L. No. 91-113, §4(a), (b)(1), Nov. 6, 1969, 83 Stat. 189, 190; Pub. L. No. 94-284, §17(a), May 11, 1976, 90 Stat. 510.

[42] Ibid.

POISON PREVENTION PACKAGING ACT -- STATUTORY REVIEW

BACKGROUND

Children under five years of age were involved in some two-thirds of the over 105,000 ingestions of drugs and potentially toxic household products reported by the national clearinghouse for poison centers in 1968.[1] During 1967, 325 children died from accidental poisoning.[2] As stated by the House Report on the Poison Prevention Packaging Act of 1970, "While the total of 325 child deaths from this cause may not appear large in proportion to the 105,000 ingestion incidents reported for this age group, it is a tragic and needless toll which dictates that every effort be employed to reduce and, if possible, eliminate it."[3] The Poison Prevention Packaging Act of 1970 (PPPA),[4] by providing for "special packaging to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting household substances,"[5] was the Congressional effort to this end.

SUBSTANCES COVERED AND STATUTORY CRITERIA

Under PPPA, the Consumer Product Safety Commission[6] (the Commission) may establish standards for

> the special packaging of any household substance if it finds that--
>
> (1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance; and

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[1] H.R. Rep. No. 91-1642, 91st Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 5326 (1970).

[2] Ibid. at 5327.

[3] Ibid. at 5327.

[4] 15 USC §1471 et seq.

[5] H.R. Rep. No. 91-1642, 91st Cong., 2nd Sess., reprinted in U.S. Code Cong. and Ad. News 5326, 5327 (1970).

[6] The functions under PPPA were originally given to the Secretary of Health, Education, and Welfare, but were transferred to the Consumer Product Safety Commission in 1972. 15 USC §2079(a).

> (2) the special packaging to be required by such standard is technically feasible, practicable, and appropriate for such substance.[7]

"Special packaging" is specifically defined under 15 USC §1471(4):

> The term 'special packaging' means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Household substance" is also defined in the Act:

> The term 'household substance' means any substance which is customarily produced or distributed for sale for consumption or use, or customarily stored, by individuals in or about the household and which is--
>
> > (A) a hazardous substance as that term is defined in section 1261(f) of this title [the Federal Hazardous Substances Act]; (B) a food, drug, or cosmetic as those terms are defined in section 321 of Title 21 [the Federal Food, Drug, and Cosmetic Act]; or (C) a substance intended for use as fuel when stored in a portable container and used in the heating, cooking, or refrigeration system of a house.[8]

In addition, the Commission is given the authority, but is not required, to establish special packaging standards, since the statute uses the words "may establish." In establishing special packaging standards, the Commission is required to consider a number of factors:

> (1) the reasonableness of such standard;
>
> (2) available scientific, medical, and engineering data concerning special packaging and concerning childhood accidental ingestions, illness, and injury caused by household substances;
>
> (3) the manufacturing practices of industries affected by this Act; and

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[7] 15 USC §1472(a).

[8] 15 USC §1471(2).

(4) the nature and use of the household substance.[9]

SUMMARY

As can be seen from these definitions and requirements, the coverage of the Act is broad, but, with the exception of certain substances intended for use as fuels,[10] the substances regulated by PPPA are all defined in and also subject to regulation under the Federal Hazardous Substances Act (FHSA)[11] or the Federal Food, Drug, and Cosmetic Act (FDCA).[12] For additional information on these definitions, the reader is referred to the statutory reviews of these Acts.

It should also be noted that 15 USC §1473 allows for packaging of a household substance which does not comply with established special packaging standards for the purpose of making such substances available to elderly or handicapped persons. Similarly, a household substance which is dispensed pursuant to an order of a licensed medical practitioner may be supplied in a non-complying package when directed by the practitioner or requested by the purchaser.[13] EPA's child resistant packaging standards under FIFRA are required to be consistent with PPPA.

Just as the definitions of most of the substances covered by PPPA are provided in other statutes, so are the enforcement provisions. Violations of special packaging standards established under PPPA make the substance packaged "misbranded" under FHSA[14] or FDCA[15] and therefore subject to the penalties provided under those statutes.

In concluding this review, it should be added that standards established pursuant to PPPA preempt state and local regulation; state and local standards must be identical to the standards established under PPPA, although stricter state and local standards will be permitted in certain circumstances.[16]

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[9] 15 USC §1472(b).

[10] 15 USC §1471(2)(c). These fuels are subject to regulation under the Federal Hazardous Substances Act if they fulfill the requirements of 15 USC §1261(p).

[11] 15 USC §1261 et seq.

[12] 21 USC §301 et seq.

[13] 15 USC §1473(b).

[14] 15 USC §1261(b).

[15] 21 USC §§343, 352, 362.

[16] 15 USC §1476.

FLAMMABLE FABRICS ACT -- STATUTORY REVIEW

Originally enacted in 1953 and subsequently amended in 1954, the Flammable Fabrics Act (FFA) was revised in 1967.[1] The purpose of this legislation is to prohibit interstate commerce in fabrics and wearing apparel which are so highly flammable that they are dangerous when worn by individuals.

Authority to issue flammability standards and associated regulations was conferred initially on the Department of Commerce; this authority was later transferred to the Consumer Product Safety Commission upon enactment of the Consumer Product Safety Act.

Regulatory authority is specified in Section 4 of the FFA. The Commission is authorized to institute regulatory proceedings whenever it finds that a standard "may be needed to protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or signficant property damage."[2] This language has not been reviewed in any legal proceedings.

Authority granted by Section 4(a) is further defined in Section 4(b). That provision describes a number of "findings" that must be made in support of a flammability regulation:

- Regulation "is needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death, injury, or significant property damage"
- Rules must be "reasonable, technologically practicable, and appropriate"
- Standards must be limited to fabrics, materials, and products which have been determined to present unreasonable risks.

Furthermore, while exemptions are authorized, they may be limited upon a finding that the fabric, material, or product "is so highly flammable as to be dangerous when used by consumers" as intended.

The FFA contains other provisions such as injunction and condemnation authority (Section 6) and specifically preempts any inconsistent state or local laws (Section 16).

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[1] 15 USC §1191 et seq.

[2] Section 4(a), 15 USC §1193(a).

CONSUMER PRODUCT SAFETY ACT -- STATUTORY REVIEW

BACKGROUND

Throughout the nineteen sixties and early nineteen seventies, numerous statutes were enacted to minimize the dangers to consumers from hazardous substances and products. The Federal Hazardous Substances Act of 1960,[1] the National Traffic and Motor Vehicle Safety Act of 1966,[2] the Flammable Fabrics Act Amendments of 1967,[3] the Poison Prevention Packaging Act of 1970,[4] and others addressed specific hazards.[5] In 1967, the National Commission on Product Safety was established to examine the adequacy of laws protecting consumers from unreasonable risks.[6] Despite the statutes covering specific hazards, the National Commission found a general absence of federal action in an area which it believed required a strong and vigorous federal presence:

> Federal products safety legislation consists of a series of isolated acts treating specific hazards in narrow product categories. No Government agency possesses general authority to ban products which harbor unreasonable risks or to require that consumer products conform to minimum safety standards.
>
> Such limited Federal authority as does exist is scattered among many agencies. Jurisdiction over a single category of products may be shared by as many as four different departments or agencies. Moreover, where it exists, Federal product safety regulation is burdened by unnecessary procedural obstacles, circumscribed investigative powers, inadequate and ill-fitting sanctions, bureaucratic lassitude, timid administration, bargain-basement budgets, distorted priorities, and misdirected technical resources.[7]

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[1] 15 USC §1261 et seq. See Statutory Review, pp. 5-1 through 5-15.

[2] 15 USC §1381 et seq.

[3] 15 USC §1191 et seq. See Statutory Review, p. 5-19.

[4] 15 USC §1471 et seq. See Statutory Review, pp. 5-16 through 5-18.

[5] See Acts cited in H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 22 (1972).

[6] H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 22 (1972).

[7] Ibid. at 22-23.

To fill this gap, Congress created the Consumer Product Safety Commission (the Commission) in 1972.[8] It was designed to reduce the estimated 20 million injuries (resulting in 110,000 permanent disabilities and 30,000 deaths) that were occurring in and around American homes every year, and to save, as far as possible, the loss of five billion dollars annually that one source placed as the cost to the economy of product-related injuries.[9] The House Committee Report introduced its discussion of the Consumer Product Safety Act (CPSA)[10] as follows:

> This legislation proposes that the Federal Government assume a major role in protecting the consumers from unreasonable risks of death, injury, or serious or frequent illness associated with the use or exposure to consumer products. To carry out that objective, this bill would create a new, independent regulatory commission with comprehensive authority to take action across the full range of consumer products to reduce or prevent product related injuries. The powers and procedural requirements contained in this legislation, for the most part, draw and improve upon concepts and practices which the Congress has previously employed in other safety laws.[11]

SUBSTANCES COVERED AND STATUTORY CRITERIA

The CPSA gives the Commission broad powers, including: to develop consumer product safety standards,[12] to ban hazardous consumer products,[13] to test consumer products,[14] to conduct research, studies, and investigations on the safety of consumer products and improving such safety,[15] to maintain an Injury Information Clearinghouse,[16] to inspect factories, warehouses, or other places where consumer products are manufactured or held,[17] to institute court actions against imminently hazardous consumer products,[18] and to order that defective or noncomplying products be remedied.[19] This section will deal with the most significant of these. The approach will be to discuss first the statutory definition and judicial interpretations of the term "consumer product" and the effect of these on the Commission's jurisdiction. Next covered will be the actions the Commission can take with respect to those consumer products that pose an "unreasonable risk of injury." Included in this will be an investigation of this risk and the term "reasonably necessary" as it applies to standards established under the CPSA. This will be followed by a discussion of some of the other requirements that the CPSA imposes on manufacturers. This review will close with a brief discussion of the effect of the CPSA on state and local regulation.

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[8] 15 USC §2035.

[9] H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 21 (1972).

[10] 15 USC §2051 *et seq.*

[11] H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 21 (1972).

[12] 15 USC §2058.

[13] 15 USC §2057.

[14] 15 USC §2054.

[15] 15 USC §2054.

[16] *Ibid.*

[17] 1[illegible] USC §2065.

[18] 15 USC §2061.

Definition of "Consumer Product" and Jurisdiction of the Commission

As can be seen, the CPSA deals mainly with consumer products, which it generally defines as:

> Any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise...[20]

There are a number of major exemptions from this definition, namely, tobacco and tobacco products, motor vehicles or motor vehicle equipment, pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act,[21] items subject to tax under 16 USC §4181[22] or any component thereof, aircraft and certain aircraft equipment, certain boats, vessels, and related equipment, drugs, devices, and cosmetics as defined in 21 USC §321(g), (h), and (i) (the Federal Food, Drug, and Cosmetic Act), and food.[23]

Since the definition of "consumer product" establishes the jurisdiction of the Commission, it has been the subject of a significant amount of litigation. Many of the cases dealing wih this issue have interpreted this definition broadly:

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[19] 15 USC §2064.

[20] 15 USC §2052(a)(1).

[21] 7 USC §136 et seq.

[22] Pistols, revolvers, firearms (other than pistols and revolvers), shells, and cartridges.

[23] 15 USC §2052(a)(1).

> The most unequivocal expression of congressional intent to be gleaned from the legislative history of the Act is that the definition of 'consumer product' be construed broadly to advance the Act's articulated purpose of protecting consumers from hazardous products. The report of the Senate Committee on Commerce, for example, points out that, rather than attempting 'to catalogue those items included within the concept of "consumer product,"' the Act's drafters chose to delineate the concept by excluding particular items from its range. Similarly, the report of the House Committee on Interstate and Foreign Commerce observes that the breadth of the definition reflects the purpose of Congress 'to vest omnibus product safety authority in a single Federal agency.' An additional factor in favor of an expansive interpretation of the Act generally is the Act's character as remedial legislation directed at a widespread, specifically identified threat to the public safety.[24]

For example, rides in amusement parks have generally been held to be consumer products,[25] despite the fact that they are large in size, are not controlled by consumers, and are not themselves sold to consumers, although one case has reached the opposite conclusion.[26] Similarly, another heavily litigated product, residential aluminum wiring systems, has been held to be a consumer product in two cases,[27] while two other cases question this ruling.[28]

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[24] Citations omitted. *Consumer Product Safety Commission (CPSC) v. Chance Manufacturing Co., Inc.*, 441 F. Supp. 228, 231 (D.C. D.C. 1977), the first two sentences of which are quoted in *Robert K. Bell Enterprises, Inc. v. CPSC*, No. 79-C-40-C (D.C.N.D. Okla. 1980). *See also* *United States v. Anaconda Co.*, 445 F. Supp. 486, 492 (D.C.D.C. 1977): "The plain words of the statute suggest an extremely broad definition of consumer products."

[25] *CPSC v. Chance Manufacturing Co., Inc.*, 441 F. Supp. 228 (D.C.D.C. 1977) (the "Zipper"); *The State Fair of Texas v. United States CPSC*, 481 F. Supp. 1070 (D.C.N.D. Tex. 1979) (aerial tramway); *Robert K. Bell Enterprises, Inc. v. CPSC*, No. 79-C-40-C (D.C.N.D. Okla. 1980) ("von Roll Sky Ride").

[26] *Walt Disney Productions v. United States CPSC*, No. 79-0170-LEW (Px) (D.C.C.D. Cal. 1979). The court in *Robert K. Bell*, *supra*, said this in its discussion of the *Disney* case: "Accordingly, this Court will follow the apparently more thoroughly researched and better-reasoned decision in *Chance*, supported by the decision in *State Fair*."

[27] *United States v. Anaconda Co.*, 445 F. Supp. 486 (D.C.D.C. 1977); *Kaiser Aluminum and Chemical Corporation v. United States CPSC*, 574 F.2d 178 (3rd Cir. 1978), *cert. denied*, 439 U.S. 881 (1978).

[28] *Kaiser Aluminum and Chemical Corporation v. U.S. CPSC*, 414 F. Supp. 1047 (D.C.Del. 1976); *CPSC v. Anaconda Co.*, 593 F.2d 1314 (D.C. Cir. 1979).

A case[29] dealing with another product, wired glass, raised several interesting issues relating to the scope of the Commission's jurisdiction. In holding that architectural glazing materials, and in particular wired glass, are consumer products, the court stated:

> The foremost limitation on the core definition of 'consumer product' specifies a requirement that the product must be 'customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer.'. . . [A] product must be 'customarily' -- not just occasionally -- produced or distributed for the use of consumers. Jurisdiction does not require a showing that a majority of product sales are to consumers, but there must be a significant marketing of the product as a distinct article of commerce for sale to consumers or for the use of consumers before the product may be considered as 'customarily' produced or distributed in that manner.[30]

The court found sufficient marketing of the architectural glazing materials in issue to give the Commission jurisdiction.

Another issue raised in the wired glass case was whether the Commission under the CPSA or the Secretary of Labor under the Occupational Safety and Health Act (OSHA) would have authority over such materials. The court found that "the Commission acted reasonably in determining that the risk of injury associated with architectural glazing materials could not be reduced 'to a sufficient extent' under OSHA and thus required regulation under CPSA."[31] The reason for this conclusion seemed to be:

> Under OSHA, which is designed to provide a safe working environment, the Secretary may not act directly against a manufacturer of an unsafe product unless that product poses a hazard to the manufacturer's employees. Obviously even a safe place of manufacture, organized to protect employees fully, may be engaged in the production of items that will be dangerous to consumers.[32]

Products that Pose an "Unreasonable Risk of Injury"

Returning now to the statute itself, if there is an "unreasonable risk of injury associated with" a consumer product, the Commission may promulgate a consumer product safety standard to prevent or reduce that risk.[33] 15 USC §2052(a)(3) provides, "The term 'risk of injury' means a risk of death, personal injury, or serious or frequent illness." A safety standard must consist of any combination of:

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[29] *ASG Industries v. CPSC*, 593 F.2d 1323 (D.C. Cir. 1979), *cert. denied*, 444 U.S. 864 (1979).

[30] Citation omitted. *Ibid.* at 1328.

[31] *Ibid.* at 1329.

[32] Footnote omitted. *Ibid.* at 1329.

[33] 15 USC §2056.

> (1) Requirements as to performance, composition, contents, design, construction, finish, or packaging of a consumer product. [and]
>
> (2) Requirements that a consumer product be marked with or accompanied by clear and adequate warnings or instructions, or requirements respecting the form of warnings or instructions.[34]

To foster innovation and competition,[35] "The requirements of such a standard (other than requirements relating to labeling, warnings, or instructions) shall, whenever feasible, be expressed in terms of performance requirements."[36].

If, however, the Commission finds that

> (1) a consumer product is being, or will be, distributed in commerce and such consumer product presents an unreasonable risk of injury; and
>
> (2) no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product,[37]

it may designate such product a "banned hazardous product." For both a consumer product safety standard and a rule declaring a product to be a banned hazardous product (both called "consumer product safety rule" or simply "rule" in the CPSA), the Commission must consider and make findings with respect to:

> (A) the degree and nature of the risk of injury the rule is designed to eliminate or reduce;
>
> (B) the approximate number of consumer products, or types or classes thereof, subject to such rule;

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[34] 15 USC §2056(a).

[35] H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 33 (1972).

[36] 15 USC §2056(a).

[37] Emphasis added. 15 USC §2057.

> (C) the need of the public for the consumer products subject to such rule, and the probable effect of such rule upon the utility, cost, or availability of such products to meet such need; and
>
> (D) any means of achieving the objective of the order while minimizing adverse effects on competition or disruption or dislocation of manufacturing and other commercial practices consistent with the public health and safety.[38]

In addition, any such "rule" must be based on these findings:

> (A) that the rule (including its effective date) is reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with such product;
>
> (B) that the promulgation of the rule is in the public interest; and
>
> (C) in the case of a rule declaring the product a banned hazardous product, that no feasible consumer product safety standard under this chapter would adequately protect the public from the unreasonable risk of injury associated with such product.[39]

As may be expected, the question of whether a rule is "reasonably necessary to eliminate or reduce an unreasonable risk of injury" has been central to some of the litigation in this area. The legislative history is quite helpful and both of the cases[40] which will be discussed here referred to it:

> It should be noted that the Commission's authority to promulgate standards under this bill is limited to instances where the hazard associated with a consumer product presents an unreasonable risk of death, injury, or serious or frequent illness. Your committee has not included a definition of 'unreasonable hazards' within this bill. Protection against unreasonable risks is central to many Federal and State safety statutes and the courts have had broad experience in interpreting the term's meaning and application. It is generally expected that the

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[38] 15 USC §2058(c)(1).

[39] 15 USC §2058(c)(2).

[40] Aqua Slide 'N' Dive Corporation v. CPSC, 569 F.2d 831 (5th Cir. 1978); D.D. Bean & Sons Co. v. CPSC, 574 F.2d 643 (1st Cir. 1978).

> determination of unreasonable hazard will involve the Commission in balancing the probability that the risk will result in harm and the gravity of such harm against the effect on the product's utility, cost and availability to the consumer. An unreasonable hazard is clearly one which can be prevented or reduced without affecting the product's utility, cost, or availability: or one which the effect on the product's utility, cost or availability is outweighed by the need to protect the public from the hazard associated with the product. There should be no implication, however, that in arriving at its determination the Commission would be required to conduct and complete a cost-benefit analysis prior to promulgating standards under this act. Of course, no standard would be expected to impose added costs or inconvenience on the consumer unless there is reasonable assurance that the frequency or severity of injuries or illnesses will be reduced.[41]

Aqua Slide 'N' Dive v. CPSC,[42] perhaps the leading case on the issues involved here, stated that:

> The legislative history, and the holdings of other cases decided under similar statutes, do discuss the meaning of 'unreasonable risk,' and indicate that term is interrelated with the 'reasonably necessary' requirement. The necessity for the standard depends upon the nature of the risk, and the reasonableness of the risk is a function of the burden a standard would impose on a user of the product.

The subject matter of Aqua Slide 'N' Dive was safety standards for swimming pool slides. The court in that case was working from the proposition that, "if any part of a standard is not 'reasonably necessary,' then the whole fails the statutory requirement unless the offending parts are set aside."[43] After reviewing legislative history, the court looked at how "unreasonable risk" was handled in cases under the Federal Hazardous Substances Act[44] and held:

> In this case, the legislative history specifies the costs to consumers that are to be considered: increases in

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[41] Emphasis added. H.R. Rep. No. 1153, 92nd Cong., 2nd Sess. 33 (1972). For a rather scathing attack on how the Commission has attempted to define "unreasonable risk," see "The Consumer Product Safety Commission: In Search of a Regulatory Pattern," 12 Colum. J.L. and Soc. Prob. 393 (1977).

[42] 569 F.2d 831, 839 (5th Cir. 1978).

[43] Ibid. at 838.

[44] See statutory review of that Act.

> price, decreased availability of a product, and also reductions in product usefulness. Implicit in this analysis is an understanding that the regulation is a feasible method of reducing the risk.
>
> * * *
>
> Also, an important predicate to Commission action is that consumers be unaware of either the severity, frequency, or ways of avoiding the risk. If consumers have accurate information, and still choose to incur the risk, then their judgment may well be reasonable.[45]

The *Aqua Slide 'N' Dive* court found significant the facts that the severity of risk is great (parapelegia); but that this risk itself is very small (about one in 10 million). It was held:

> Given the severity of the injury, however, and the precedent of other cases, it seems likely that a standard which actually promised to reduce the risk without unduly hampering the availability of the slides or decreasing their utility could render this risk 'unreasonable.' The question then is whether the specific provisions of the standard which Aqua Slide challenges have been shown to accomplish that task.[46]

In answering this question, the court posed another:

> In weighing the 'reasonable necessity' for the signs, the crucial question then, is whether the benefit has a reasonable relationship to the disadvantages the sign requirement imposes.[47]

With respect to the warning signs and ladder chain in issue in that case, the court held that the Commission had not shown this relationship; there was not sufficient support for the balance it struck between benefits and costs. The rest of the standard was upheld.

This balancing test approach was also specifically adopted by the court in *D.D. Bean & Sons Co. v. CPSC*,[48] dealing with safety standards for matchbooks. The court stated:

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[45] Citations omitted. *Aqua Slide 'N' Dive Corporation v. CPSC*, 569 F.2d 831, 839 (5th Cir. 1978).

[46] *Ibid.* at 840.

[47] *Ibid.* at 842.

[48] 574 F.2d 643 (1st Cir. 1978).

> Only after the existence of a hazard and the likelihood of its reduction at a reasonable cost have been established by the Commission may it be said that the requirements are 'reasonably necessary.'
>
> * * *
>
> [A determination of 'reasonably necessary'] entails a balancing of the magnitude of the likely reduction in hazards to consumers against the increased cost to consumers and manufacturers.[49]

In that case, the "general" requirements of the safety standard were upheld, while the "performance" requirements were set aside based on this balancing test.

Other Major Provisions of the CPSA

Returning once more to the statute, consumer product safety standards and the appellation "banned hazardous product" are important because 15 USC §2068 makes it unlawful to "manufacture for sale, offer for sale, distribute in commerce,[50] or import into the United States" any consumer product which "is not in conformity with an applicable consumer product safety standard" or "has been declared a banned hazardous product." Violations of this section may carry severe civil and criminal penalties.[51]

In addition to these penalties, manufacturers, distributors, and retailers of consumer products are subject to penalties[52] for failing to report to the Commission:

> [I]nformation which reasonably supports the conclusion that such product--
>
> (1) fails to comply with an applicable consumer product safety rule; or
>
> (2) contains a defect which could create a substantial product hazard. . . .[53]

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[49] Ibid. at 649.

[50] Defined broadly in 15 USC §2052(a)(11).

[51] 15 USC §2069, 2070.

[52] 15 USC §2068(a)(4) and 2069, 2070.

[53] 15 USC §2064(b).

A "substantial product hazard" is defined as

> (1) a failure to comply with an applicable consumer product safety rule which creates a substantial risk of injury to the public, or
>
> (2) a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.[54]

This phrase is important not only for the reporting requirements just mentioned, but also because the Commission may order notification to the public, manufacturers, distributors, or retailers, and/or owners of the product if it determines after a hearing that such a hazard exists and that notification is necessary to adequately protect the public.[55] The Commission may also order a manufacturer, distributor, or retailer to take additional action, if in the public interest, such as repair, replacement, or refund of the purchase price (the person to whom the order is directed may elect among these options).[56] Failure to comply with either type of order may carry stiff penalties.[57]

Labeling regulations may be issued under the authority of either Section 7 or Section 27(e) of the CPSA. The Section 7 authority is limited to consumer products which present an unreasonable risk and requires the CPSC to formally make specific findings. Section 27(e), on the other hand, is applicable to any consumer products and does not require the specific findings listed in Section 9(c) of the CPSA. Section 27(e) was used in the rule-making on urea-formaldehyde foam insulation (see further discussion in CPSA regulatory review).

In closing, the relationship between the CPSA and state and local regulations should be discussed. 15 USC §2075 provides that state and local governments may, in general, establish or continue in effect standards relating to consumer product safety designed to deal with the same risk of injury as an existing federal standard only if the state or local standard is identical to the applicable federal standard. Under certain circumstances, state and local standards which differ from federal standards will be allowed.[58]

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[54] 15 USC §2064(a).

[55] 15 USC §2064(c).

[56] 15 USC §2064(d).

[57] 15 USC §2068(a)(5) and 2069, 2070.

[58] 15 USC §2075.

SUMMARY

Under the CPSA, the Consumer Product Safety Commission is given broad powers to regulate consumer products. The Commission is authorized, among other things, to develop standards for consumer products and to ban those products which can not be made reasonably safe even with such standards. The major points of controversy which the courts have been asked to settle are (1) what is included in the term "consumer product" and (2) what consumer product safety rules are "reasonably necessary to eliminate or reduce an unreasonable risk of injury associated with" a consumer product. The judicial response has been to interpret the term "consumer product" rather broadly and to employ a balancing test in evaluating consumer product safety rules, balancing the reduction in hazard to the consumer on the one hand against the increased costs and other disadvantages to consumers and manufacturers on the other hand.

FEDERAL HAZARDOUS SUBSTANCES ACT, POISON PREVENTION PACKAGING ACT, AND CONSUMER PRODUCT SAFETY ACT -- REGULATORY REVIEWS

The Consumer Product Safety Commission (CPSC) regulates hazardous substances under three statutory authorities:

- Federal Hazardous Substances Act,
- Poison Prevention Packaging Act,
- Flammable Fabrics Act, and
- Consumer Product Safety Act.

The following discussion reviews the regulations promulgated under each Act, examines the criteria used to designate substances for regulation, and identifies the regulated substances. An overview of CPSC regulatory authority is provided in Exhibit 5-3.

EXHIBIT 5-3

OVERVIEW OF CONSUMER PRODUCT SAFETY COMMISSION REGULATORY AUTHORITY

STATUTE	REGULATED SUBSTANCES	TYPE OF ACTION AUTHORIZED	CRITERIA	STANDARDS BASED ON	BURDEN OF PROOF	COST BENEFIT ANALYSIS
Federal Hazardous Substances Act	Hazardous substances for household use and in toys	• Ban on substance • Special Labeling • Listing of hazardous substances	Substance may cause substantial personal injury or illness	• Results of animal or human exposure studies • Consumer complaints; • Reported deaths; and, • Regulatory action by other agencies.	CPSC	No
Poison Prevention Packaging Act	Household substances, including drugs	• Special Packaging	Protection of young children from serious personal injury or illness	• Available scientific, medical, and engineering data; • Nature and use of the substance; and • Technical feasibility, practicality and appropriateness of special packaging	CPSC, however petitioner for exemption must prove safety of product	Yes
Consumer Product Safety Act	Consumer Products	• Ban on product • Special Labeling Requirements • Product safety standards • Other rules	Product presents an unreasonable risk of injury; standard is reasonably necessary; if no feasible standard, ban is authorized	• Health effects data--human and animal exposure studies; • Degree and nature of risk involved; • Significance of exposure; and Economic considerations	CPSC	Yes

THE FEDERAL HAZARDOUS SUBSTANCES ACT -- REGULATORY REVIEW

INTRODUCTION

Authority to administer the Federal Hazardous Substances Act (FHSA) was transferred from the Department of Health, Education, and Welfare to CPSC in 1972. At that time, certain chemicals and products were already designated hazardous according to the following four categories.

- products declared to be hazardous substances under section 3(a) of the Act (16 CFR 1500.12);
- strong sensitizers (16 CFR 1500.13);
- products requiring special labeling under section 3(b) of the Act (16 CFR 1500.14); and
- banned hazardous substances (16 CFR 1500.17).

Since 1972, CPSC has not substantially augmented these lists and has issued FHSA regulations primarily for products intended for use by children (toys, cribs, rattles, pacifiers, and bicycles). For various reasons the Commission tends to regulate products containing hazardous substances under the Consumer Product Safety Act (CPSA) instead of the FHSA, and as a result has not often been required to utilize criteria for designating products containing such substances under the FHSA.[1] Nevertheless, CPSC is responsible for regulating the four categories of hazardous substances that were already designated or listed in the FHSA regulations (16 CFR 1500) as transferred in 1972. Exhibit 5-4 provides a chronology of the regulations and related activities.

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[1] Although CPSC had been receiving petitions to regulate products containing hazardous substances under the FHSA, it decided instead to regulate the products under the Consumer Product Safety Act. For example, CPSC received petitions to regulate consumer patching compounds containing respirable free-form asbestos under the FHSA. But because the rulemaking proceedings would be significantly shorter and more public participation would be allowed under the CPSA than under the FHSA, and because CPSA provides additional incentives to comply in the form of civil penalties, CPSC decided to regulate the consumer patching compounds under the CPSA (42 FR 63354, December 15, 1977). CPSC adopted this strategy in two other cases: lead-based paint (41 FR 33637, August 10, 1976) and chlorofluorocarbon propellants (42 FR 21807, April 29, 1979).

EXHIBIT 5-4

FEDERAL HAZARDOUS SUBSTANCES ACT
REGULATORY CHRONOLOGY

ACTION	CITE
Carbon tetrachloride banned as a hazardous product by FDA	16 CFR 1500.17
Charcoal briquettes regulated under sections 3(a) and 3(b) by FDA	16 CFR 1500.12 16 CFR 1500.14
Liquid drain cleaners containing sodium and potassium hydroxide banned as hazardous products by FDA unless contained in child-resistant packaging	16 CFR 1500.17
Charcoal briquettes subjected to sections 3(a) and 3(b) labeling requirements by FDA	16 CFR 1500.12 16 CFR 1500.14
General-use asbestos-containing garments banned as hazardous products by FDA	16 CFR 1500.17
Self-pressurized products containing vinyl chloride monomer banned as hazardous products by CPSC	16 CFR 1500.17

REGULATORY CRITERIA

As indicated by the regulatory chronology in Exhibit 5-4, the most recent chemical substance to be regulated by CPSC under the Federal Hazardous Substances Act was vinyl chloride monomer in 1974. The fact that CPSC has chosen in recent years to regulate chemical substances under the Consumer Product Safety Act (see footnote 1) instead of the FHSA tempers somewhat the usefulness of analyzing the FHSA's criteria for designating subtances as hazardous. However, in view of the Supreme Court's recent benzene ruling, CPSC may find it necessary to resort to the lengthy proceedings mandated by the FHSA in establishing sufficient grounds for promulgating hazardous substances rules. If this trend develops, the FHSA's designation criteria for hazardous substances will be of critical importance. Even without such a development, a review of the FHSA's designation criteria is worthwhile because it provides a substantive basis for discussing any potential coordination among agencies of hazardous substances designation.

A Substance Must Cause Substantial Personal Injury or Illness to be Declared Hazardous

By statutory definition, a hazardous substance is a substance or mixture of substances that may cause "substantial personal injury or illness." While this criterion leaves much to be interpreted (i.e., the precise meaning of the term "substantial") both CPSC and FDA have demonstrated in various ways that substances they designated for regulation may cause substantial personal injury or illness. Usually regulation was imposed when exposure to a particular substance had been known to lead to death. In some instances, however, a possible link with death was not clearly established, and expert recommendations and other agency standards were relied upon to establish the existence of a probable hazard. The CPSC has never stated that the phrase means only death or that regulatory action will only be taken with respect to death situations.

Historically, both CPSC and FDA based their findings of substantial injury and illness on one or more of the following factors:

- Expert testimony or medical literature concerning the results of either animal or human exposure studies, or both, which indicated potential adverse health effects;
- Complaints directed to the agency supporting claims that a substance or product was associated with adverse health effects;
- Reported deaths; and
- Regulatory action taken by other government agencies.

As noted in the last section of the report, Methods for Evaluating Hazard Criteria, the FHSA regulations provide specific methods for testing toxic substances, primary irritants, eye irritants, and flammability. For other types of hazards, CPSC and FDA relied on more general evidence provided on a case-by-case basis. The Federal Register notices of proposed rules did not document these tests to the degree of detail as provided in the FHSA regulations. Thus, there is no way to evaluate the consistency with which tests were used to support a need for regulation.

CPSC has Considerable Leeway in Designating a Substance as Hazardous

Once CPSC establishes jurisdiction over a particular substance, it has a fair amount of flexibility in determining whether a substance is hazardous or not. As evidenced by FDA's previous regulatory actions under the FHSA, as long as there was sufficient evidence that a substance may cause "substantial" injury or illness, then the substance could be declared hazardous. Although there are no uniform rules as to what constitutes sufficient evidence or substantial injury, it is not clear that such rules are necessary. Because of the differing nature of health effects from exposure to different hazardous substances and because of the varying degrees to which individuals may react to a given substance, it is important that CPSC be allowed some amount of regulatory flexibility in declaring a substance to be hazardous.

PRODUCTS DECLARED TO BE HAZARDOUS SUBSTANCES - 16 CFR SECTION 1500.12

Section 3(a) of the FHSA authorizes CPSC to declare as hazardous a substance or mixture of substances that meets the "hazardous substance" definition of Section 2(f)(1)(A) of the Act (also restated in 16 CFR 1500.3(b)). The Act categorizes hazardous substances very specifically, as discussed in the statutory review. However, terms within the definition of "hazardous substances", such as "highly toxic", "corrosive", etc., are defined in 16 CFR 1500.3(c). The definitions and further explanations provide criteria for CPSC to decide whether to designate a substance as hazardous.

For example, the term "highly toxic" refers to any substance which "produces death within fourteen days in half or more than half of a group of ten or more laboratory white rats each weighing between two and three hundred grams...." (16 CFR 1500.3(b)(6)).

- Thus, if CPSC possessed data which indicated that exposure (also defined in the regulations) to a substance produced death within fourteen days in at least half of a group of laboratory white rats, then the Commission could declare such a substance to be highly toxic and thus subject to the labeling regulations for hazardous substance under FHSA Section 2(p)(1).

The label must bear the common name of the hazardous substance, the chemical name of the substance if there is no common name, or the generic name if permitted by CPSC. In addition, the word "Danger" must appear on the label for substances which are extremely flammable, corrosive, or highly toxic. The word "Warning" or "Caution" must appear on the labels of all other hazardous substances. Other labeling requirements under section 16 CFR 1500.3(b)(4) involve identifying the principal hazards and providing precautionary measures, antidotal information, handling instructions, and other important warnings.

The labeling regulations state that a hazardous substance intended, or packaged in a form suitable, for use in the household or by children will be termed "misbranded" if it does not bear a label that warns the consumer of potential hazards posed by the substance. If a declared hazardous substance is deemed a misbranded hazardous substance it is subject to prohibition, penalties, or seizures under the FHSA.

If CPSC determines that feasible cautionary labeling cannot adequately protect the public from the hazard posed by the substance, it may declare a product to be a "banned hazardous product."

The FHSA regulations list one product declared to be a hazardous substance under section 3(a) of the Act: charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking or heating (16 CFR 1500.12). This product was declared to be a hazardous substance by the Department of Health, Education, and Welfare's Food and Drug Administration (FDA), which had original jurisdiction over the FHSA.

In 1970, FDA proposed that charcoal briquettes be subject to the labeling requirements of section 3(a) because when burned, this product is capable of producing "personal injury and death to man through reasonably foreseeable handling and use" (35 FR 13887, September 2, 1970). FDA had reviewed death certificates and information from other sources which indicated that at least 37 fatalities from carbon monoxide poisoning had occurred because individuals used the briquettes for cooking or heating purposes indoors, in tents, or in similar confined areas. Based on this evidence, FDA concluded that individuals would be unlikely to burn charcoal in confined spaces if they knew it could cause death. On August 11, 1971, FDA issued a final rule to list charcoal briquettes as a hazardous substance under section 3(a) of the Act (36 FR 14729).

LISTING OF STRONG SENSITIZERS - 16 CFR SECTION 1500.13

The term "hazardous substance" may apply to any substance or mixture of substances that is a strong sensitizer. 16 CFR 1500.3(b)(9) of the FHSA regulations defines strong sensitizer as "a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance." (emphasis added.) As a hazardous substance, a strong sensitizer is subject to the labeling requirements of the FHSA, including misbranded hazardous substances and banned hazardous substances.

The FHSA regulations list five strong sensitizers (see Exhibit 5-5). Since CPSC assumed administrative responsibility for the FHSA, no new strong sensitizers have been added to the list (16 CFR 1500.13).

In designating a substance as a strong sensitizer, CPSC must consider the frequency of occurrence and severity of the reaction, and find that the substance has a significant potential for causing hypersensitivity. (16 CFR 1500.3(b)(9)).

PRODUCTS REQUIRING SPECIAL LABELING - 16 CFR SECTION 1500.14

For substances or mixtures of substances declared to be hazardous, the labeling requirements of section 2(p)(1) may be inadequate to protect the general public health and safety. Thus, section 3(b) of the FHSA allows CPSC to establish reasonable variations or additional labeling requirements as necessary. The same criterion for designating substances as hazardous under 16 CFR Section 1500.3(b)(4) applies to this category. In addition, the labeling requirements of 2(p)(1) must be deemed inadequate before CPSC can designate a hazardous product as requiring special labeling under section 3(b).

EXHIBIT 5-5

SUBSTANCES AND ARTICLES DESIGNATED UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT

Regulation	Substance/Product	Designation Criteria
1500.12 Products declared to be hazardous substances under Section 3(a) of the act	Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking and heating	Capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use.
1500.13 Listing of "strong sensitizer" substances	(1) Paraphenylenediamine and products containing it. (2) Powedered orris root and products containing it. (3) Epoxy resins systems containing in any concentration ethylenediamine, diethylenetriamine, and diglycidyl ethers of molecular weight of less than 200. (4) Formaldehyde and products containing 1 percent or more of formaldehyde. (5) Oil of bergamot and products containing 2 percent or more of oil of bergamot.	Meets statutory definition of strong sensitizer: a substance which will cause on normal living tissue through an allergic or photodynamic process a hypersensitivity which becomes evident on reapplication of the same substance and which is designated by the Secretary. Designation based upon consideration of the frequency of occurrence and severity of the reaction. Substance must have a significant potential for causing hypersensitivity."
1500.14 Products requiring special labeling under Section 3(b) of the act	(1) Diethylene glycol and mixture containing 10 percent or more by weight of diethylene glycol. (2) Ethylene glycol and mixtures containing 10 percent or more by weight of ethylene glycol. (3) Products containing 5 percent or more by weight of of benzene (also known as benzol) and products containing 10 percent or more by weight of toluene (also known as toluol), xylene (also known as xylol), or petroleum distillates such as kerosene, mineral seal oil, naphtha, gasoline, and related petroleum distillates. (4) Methyl alcohol (methanol) and mixtures containing 4 percent or more by weight of methyl alcohol (methanol). (5) Turpentine (including gum turpentine, gum spirits of turpentine, steam-distilled wood turpentine, sulfate wood turpentine, and destructively distilled wood turpentine) and mixture containing 10 percent or more by weight of such turpentine. (6) Charcoal briquettes and other forms of charcoal in containers for retail sale and intended for cooking and heating. (7) Fireworks devices.	Capable of causing substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use. Regular labeling requirements of section 2(p)(1) not adequate for protection of public health and safety in view of the special hazards presented by these products.

EXHIBIT 5-5 (Continued)

SUBSTANCES AND ARTICLES DESIGNATED UNDER THE FEDERAL HAZARDOUS SUBSTANCES ACT

Regulation	Substance/Product	Designation Criteria
1500.17 banned hazardous	(1) Water repellant treatments that are extremely flammable	These substances possess such a degree or nature of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce.
	(2) Carbon tetrachloride and mixtures containing it	
	(3) Certain fireworks devices intended to produce audible effects	
	(4) Liquid drain cleaners containing 10% or more by weight of sodium and/or potassium hydroxide unless packaged in accordance with PPPA standards	
	(5) Products containing soluble cyanide salts	
	(6) Paints or other similar surface-coating materials containing lead	
	(7) General use garments containing asbestos	
	(8) Certain firecrackers designed to produce audible effects	
	(9) All fireworks devices, other than firecrackers, including kits and components intended to produce such fireworks, not otherwise banned under the Act, that do not comply with 16 CFR Section 1507.	
	(10) Self-pressurized products intended or suitable for household use that contain vinyl chloride monomer.	

The FHSA regulations identify seven products that require special labeling including the label content and size where appropriate (16 CFR 1500.14). Exhibit 5-5 lists the seven products.

BANNED HAZARDOUS SUBSTANCES - 16 CFR SECTION 1500.17

In order to be classified as a banned hazardous substance, a product must at first meet the 16 CFR 1500.3(b)(4) definition of "hazardous substance." Beyond that, if the degree and nature of the hazards are such that adequate cautionary labeling cannot provide adequate protection, then the public health and safety may be protected by a ban on the substance.

The FHSA regulations list ten banned hazardous substances (see Exhibit 5-5) (16 CFR 1500.17). With the exception of self-pressurized products containing vinyl chloride monomer, certain firework devices, and firecrackers, all of the substances on the list were banned by the FDA. For purposes of contrast and comparison, we examine CPSC's and FDA's banning procedures in the following cases:

- Self-pressurized products containing vinyl chloride monomer;
- General-use garments containing asbestos;
- Liquid drain cleaners containing sodium and potassium hydrochloride; and
- Carbon tetrachloride and mixtures containing it.

Self-Pressurized Products Containing Vinyl Chloride Monomer (CPSC)

In 1974, CPSC added self-pressurized products containing vinyl chloride monomer to FDA's original list of banned hazardous substances. CPSC based its decision to classify such products as banned hazardous substances on the following factors:

- Reports of deaths of several chemical company employees who had been exposed to vinyl chloride monomer;
- Results of animal studies linking vinyl chloride monomer exposure to liver tumors;
- Testimony of medical experts and information contained in medical literature in support of the position that vinyl chloride monomer is associated with liver cancer and with other diseases.

- Information contained in an Occupational Safety and Health Administration notice of proposed rulemaking applicable to the use of vinyl chloride monomer as an ingredient of self-pressurized drug and cosmetic products;
- Animal studies cited by the Environmental Protection Agency in ordering an emergency suspension of pesticide spray products containing vinyl chloride. Results of the studies indicated that angiosarcoma of the liver had been observed in mice exposed to low concentrations (50 parts per million) of vinyl chloride; and
- Exposure studies which indicated that vinyl chloride may be present in the air in concentrations as great as 400 parts per million after household use of self-pressurized containers with vinyl chloride in the propellant.

From the Federal Register notice which summarized these findings (39 FR 30012, August 21, 1974), it is apparent that CPSC based its designation of certain vinyl chloride monomer products as banned hazardous substances on two major criteria: health effects and exposure significance. The health effects (primarily malignant tumors) were documented in animal studies and actual cases indicating a relatively high mortality rate among chemical company employees exposed to vinyl chloride monomer. CPSC considered these health effects serious enough to classify vinyl chloride monomer as a "hazardous substance." Under section 2(q)(1)(B) of the FHSA, CPSC further classified vinyl chloride monomer as a "banned hazardous substance" because the cautionary labeling required under the act would not be sufficient to protect the public health and safety from the hazards associated with exposure to vinyl chloride.

The exposure studies also led CPSC to conclude that the risk of serious personal illness from the household use of vinyl chloride monomer products was not minimal. The Commission found that the concentrations of vinyl chloride in the air after household use of certain vinyl chloride monomer products may have been as much as eight times the concentration which induced tumors in mice.

General Use Garments Containing Asbestos (FDA)

In much the same procedural pattern followed by CPSC in the vinyl chloride case, FDA proposed to ban garments for general use containing asbestos because (1) they presented an unwarranted hazard of toxicity and (2) even cautionary labeling would be inadequate to protect the public health and safety from such hazards (37 FR 3643, February 18, 1972).

Certain garments constructed from imported fabric that contained eight percent asbestos were being marketed in the United States. Upon learning this, FDA convened an ad hoc committee of five asbestos toxicity experts to evaluate the health risks associated with the garments. The committee concluded that the use of asbestos in garments for general use presented unwarranted hazards and recommended that appropriate action be taken.

Based on the committee's findings and the OSHA asbestos dust standard (36 FR 23208, December 7, 1971), FDA classified general-use garments containing asbestos as a banned hazardous substance (37 FR 3645, February 18, 1972).

Liquid Drain Cleaners Containing Sodium and Potassium Hydroxide (FDA)

In a proposal to ban liquid drain cleaners containing 10 percent or more of sodium and potassium hydroxide, FDA cited its own investigations into consumer complaints, death certificate reviews, and animal studies as major sources of information concerning the hazards associated with the product (35 FR 17746, November 18, 1970). These sources indicated that the liquid drain cleaners caused a large number of serious injuries and some deaths following accidental ingestion of these solutions by children. In 1969, 169 accidental ingestions were reported to FDA; 51 of these cases required hospitalization.

Animal studies showed that contact with less than one teaspoonful of a strong sodium hydroxide solution produced in less than three seconds full thickness destruction of the esophagus. No antidote would be of any value in such an event.

FDA concluded that despite existing requirements to label the drain cleaners as poisonous and to provide other cautionary information, accidental ingestion could still occur and result in tragic deaths. Because of the degree and nature of the hazard involved in the presence of such drain cleaners in or around the household, FDA eventually banned the product from the market. The FHSA regulations exempt such liquid drain cleaners from the ban if they are packaged to prevent children under the age of five from gaining access to the container's contents (16 CFR 1500.17).

Carbon Tetrachloride and Mixtures Containing It (FDA)

Used primarily in industrial applications, carbon tetrachloride is an extremely toxic substance capable of causing extensive damage to the liver, kidneys, lungs, and heart upon ingestion, inhalation or absorption through skin and mucous membranes. Ingestion of three to five cc of this substance may be fatal. One teaspoonful of carbon tetrachloride placed in an unventilated 6'x10'x8' room will vaporize and produce a concentration of 100 ppm. One-half pint would produce a concentration of 4,420 ppm which could prove fatal to most individuals, depending on the length of exposure.

In 1970, FDA proposed to classify as banned hazardous substances carbon tetrachloride and mixtures containing it (35 FR 4001, March 3, 1970). FDA based part of its decision to ban the substance on evidence introduced at a public hearing that was held to determine the degree or nature of hazards presented by carbon tetrachloride.

At the public hearing, FDA was informed that consumers have been and will continue to be exposed unknowingly to the dangers of carbon tetrachloride in the home when it is used as a cleaning agent and in hobby work. Without adequate ventilation, exposure would probably result in injury to the user. Because adequate ventilation in the home would require sophisticated exhaust systems and because it is unlikely that consumers would have these systems installed in their homes, FDA concluded that the best solution to the problem was a ban.

FDA proposed to ban carbon tetrachloride and mixtures containing the substance upon finding that carbon tetrachloride is a toxic substance which has the capacity to produce personal injury, illness and death; it is packaged in a form suitable for household use; and that labeling would not be sufficient to protect users from the adverse effects of carbon tetrachloride (35 FR 4001, March 3, 1970).

TEST METHODS FOR EVALUATING HAZARD CRITERIA

The FHSA regulations provide specific test methods for determining toxic substances, primary irritants, eye irritants, and flammability.

An acute dermal toxicity test on laboratory animals is employed for toxic substances. The regulations give instructions on preparing the test animal and also provide test procedures for calculating a dose that would be fatal to 50 percent of the animals tested (16 CFR 1500.40).

Primary skin irritations are measured by a patch-test technique (16 CFR 1500.41).

For eye irritants the test substance is placed in one eye of an albino rabbit; the other eye serves as a control. To check for positive or negative reactions, the grade of oculation is measured at different time intervals (16 CFR 1500.42).

A Tagliabue open-cup apparatus is used to determine the flashpoint of volatile flammable materials (16 CFR 1500.43). Other tests involve the determination of extremely flammable and flammable solids (16 CFR 1500.44), extremely flammable and flammable contents of self-pressurized containers (16 CFR 1500.45), and the flashpoint of extremely flammable contents of self-pressurized containers (16 CFR 1500.46).

POISON PREVENTION PACKAGING ACT -- REGULATORY REVIEW

INTRODUCTION

Under Section 3(a) of the Poison Prevention Packaging Act (PPPA), CPSC may require special packaging of any "household substance" if special packaging is needed to prevent children from gaining access to the substance. This provision of the Act is intended to "protect children from serious personal injury or serious illness" resulting from handling, using, or ingesting such substances. Regulations may be issued for hazardous substances subject to the FHSA as well as food, drugs, and cosmetics (Section 2(2)).

Most of the regulated substances were designated soon after the PPPA was passed in 1970; the evidence of accidental ingestion by children under five years of age around that time was undeniably alarming. As many as 2,092 cases of ingestion were reported between 1968 and 1970 to the National Clearinghouse for Poison Control Centers for just one substance: turpentine. Of these ingestions, 249 hospitalizations were reported. Two ingestions resulted in death.

REGULATORY CRITERIA

The Consumer Product Safety Commission has followed a clear pattern in promulgating special packaging rules for household substances. Basically, the steps involved are:

- Identify that the degree or nature of the hazard to children (by reason of its packaging) is such that special packaging is required; and
- Find that the special packaging to be required by a standard is feasible, practicable, and appropriate.

In general, the first step has been accomplished by showing that children under five years of age have had access to and ingested household substances, and that the accidental ingestion resulted in adverse health effects. As evidence of accidental ingestions, CPSC and FDA have used data from the National Clearinghouse for Poison Control Centers which indicate the number of ingestions and hospitalizations within a given time span by type of substance ingested. Other sources of information, typically medical literature, confirm the adverse health effects of ingesting such substances. There is no minimum number of ingestions or frequency of ingestions below which CPSC can not take regulatory action. There apparently also is no minimum adverse effect that must occur before special packaging is considered.

In the second step, CPSC is required to find that the proposed special packaging is feasible, practicable, and appropriate. Finding feasibility has involved citing the fact that a number of package designs meet the effectiveness requirements of special packaging as specified in 16 CFR 1700.20. This regulation sets up the protocol for testing the ability of special packaging to resist opening by children.

Practicability has meant that the special packaging is adaptable to modern mass production and assembly line techniques. Appropriateness has meant that the packaging is available in forms that are not detrimental to the integrity of the substance and that do not interfere with its storage and use.

Although it is entitled the Poison Prevention Packaging Act, neither the Act nor its regulations explicitly provide a definition of the term "poison." Instead the regulations set up criteria to decide if the substance should be regulated. The methods used to establish the "serious personal injury or serious illness" criterion are implied in the regulatory provisions for exemptions under the Act. In order to claim an exemption from the special packaging requirement, a petitioner must follow certain guidelines. These guidelines are indicative of the information that CPSC would consider in deciding which substances are subject to regulation under the PPPA and which substances are exempt.

For example, in claiming an exemption, a petitioner must justify how the lack of toxicity and the lack of adverse human experience supports the exemption. When CPSC processes an exemption claim, it considers a petition to be complete if the petition includes, among other things, "all available information concerning human experience data" and "relevant experimental data (both human and animal)" (16 CFR 1702.3(a)(2)). An incomplete petition may be returned to the submitter for additional information or clarification. If the submitter does not take steps to complete the petition within a reasonable period of time, CPSC has the authority to close the petition without taking regulatory action.

According to the regulations, "human experience data" refers to "reports pertaining to human use of the particular substance and involving adverse reports of personal injury, illness, and significant allergenicity. (16 CFR 1702.8). Human experience data may come from the following sources as listed in Part 1702.8 of the PPPA regulations:

- Poison Control Centers;
- Manufacturers of the product who receive physician, hospital, or consumer reports of adverse reactions to the product;
- Medical, pharmacological, and toxicological literature;
- Food and Drug Administration reports.

"Relevant experimental data" refer to data generated in controlled tests of both animals and humans in order to evaluate the biological effects of a substance. CPSC has a precise method for determining the minimum toxicological evaluation necessary for a particular household substance, indicating the criteria CPSC uses in deciding whether to regulate or exempt a substance. Because CPSC considers the amount of data needed for a particular substance to be proportional to the expected exposure of man to that substance, it has separated the relevant experimental data requirements into three subsections (16 CFR 1702.9):

1. Minimum acute animal toxicity data which must be submitted for all petitions;
2. Additional data which must be submitted for drug products and all other household substances which are normally intended to be used in or on the human body; and
3. Additional data which should be submitted for substances not intended for use in or on the human or animal body.

REGULATED SUBSTANCES

CPSC regulates 15 substances or categories of substances under the PPPA as shown in Exhibit 5-6. The Food and Drug Administration promulgated PPPA regulations for the first eleven substances while administration of the Act was under its authority.

Six of the fifteen substances currently regulated by CPSC are substances that are intended for oral ingestion in controlled doses. Improperly packaged, they present a potential for accidental ingestion by children in doses that may be harmful even in amounts normally prescribed for adults. The remaining substances regulated by CPSC are either common household products like furniture polish or substances used as ingredients in common household products. Improperly packaged, these products and substances also pose serious potential hazards.

CPSC, in its most recent rulemaking activity under the PPPA, promulgated requirements for child-resistant packaging of acetaminophen preparations on August 31, 1979 (44 FR 51211). The rule applies to such preparations that are in a dosage form intended for oral administration and that contain more than one gram of acetaminophen in a single package.

Acetaminophen Rulemaking. CPSC reviewed medical literature, injury data, and death certificates before concluding that a special packaging regulation was needed for acetaminophen in order to protect children under five years of age. Ingestion of excessive amounts of acetaminophen can cause serious toxic effects including liver damage and deterioration of liver function. Overdose cases could prove fatal. In a response to comments regarding its proposed special packaging requirements for acetaminophen, CPSC indicated that the consequence of death was not a necessary criterion for justifying a special packaging rule (44 FR 51214, August 31, 1979). The commenter had questioned the propriety of establishing a causal link between reported deaths and

EXHIBIT 5-6

SUBSTANCES DESIGNATED FOR SPECIAL PACKAGING REQUIREMENTS
16 CFR 1700.14

1. Aspirin and preparations containing aspirin.

2. Liquid furniture polish (nonemulsion type) containing 10 percent or more of mineral seal oil and/or other petro- leum distillates and having viscosity of less than 100 Saybolt universal seconds at 100°F, other than those packaged in pressurized spray containers.

3. Liquid preparations containing more than 5 percent by weight of methyl salicylate (wintergreen oil), other than those packaged in pressurized spray containers.

4. Controlled substances subject to the Drug Abuse Prevention and Control Act of 1970.

5. Household substances containing sodium and/or potassium hydroxide. Includes household lye, oven cleaners, and drain and toilet cleaners.

6. Household substances in liquid form containing 10 percent or more of turpentine.

7. Certain liquid kindling and/or illuminating preparations containing 10 percent or more of petroleum distillates, and having viscosity of less than 100 Saybolt universal seconds at 100°F.

8. Household substances in liquid form containing methyl alcohol (methanol).

9. Household substances containing 10% or more by weight of sulfuric acid.

10. Human prescription drugs in oral dosage form.

11. Household substances containing 10% or more by weight of ethylene glycol, including permanent-type auto antifreeze and certain automotive brake fluids.

12. Iron containing drugs.

13. Dietary Supplements containing iron.

14. Liquid paint solvent preparations containing petroleum distillates, benzene, toluene, xylene, or combinations thereof. Includes thinners, removers, brush cleaners for paint, varnish, lacquer, and similar surface coating materials.

15. Acetaminophen.

acetaminophen ingestion. CPSC responded that "in any event, there is ample evidence of non-lethal adverse effects associated wih acetaminophen sufficient to warrant the special packaging requirement."

CPSC's promulgation of final rules for child-resistant packaging of acetaminophen preparations involved the following findings in accordance with the PPPA's requirements:

- Serious illness or injury. From 1969 to 1976 there were reported ingestions of acetaminophen-containing products among children under five years of age. Four-hundred sixty-two of these cases exhibited symptoms; 129 of these required hospitalization. Two of the 6,523 cases resulted in death. Data from another source indicated that for 1976 and 1977, there were 901 reported ingestions of acetaminophen-containing products; 17 resulted in hospitalization. Reports in the medical literature state that acute acetaminophen ingestions are highly toxic. These studies, plus the data showing numerous ingestions led CPSC to conclude that acetaminophen was packaged in such a way as to produce potential serious personal injury or serious illness in children under five years of age.

- Technical feasibility, practicability, and appropriateness. CPSC found that acetaminophen is marketed in tablets, powders, and capsules, and in various liquid formulations. For each form of the product there are numerous suitable package designs in accordance with the poison packaging prevention standards (16 CFR 1700.15(b)). As a result, special packaging requirements for acetaminophen would be technically feasible.

CPSC also found that the proposed requirements were practicable as there would be no major supply or procurement problems for the packagers of acetaminophen products, nor for the manufacturers of child-resistant packaging. Finally, CPSC found that special packaging was appropriate because packaging is available that would not be detrimental to the integrity of the substance and that would not interfere with its storage and use.

In summary, CPSC based its promulgation of child-resistant packaging requirements on the following considerations:

- the reasonableness of the standard;

- available scientific, medical, and engineering data;

- the manufacturing practices of industries affected by the standard; and

- the nature and use of acetaminophen.

FLAMMABLE FABRICS ACT -- REGULATORY REVIEW

OVERVIEW

Flammable Fabrics Act (FFA) regulations promulgated by the Consumer Product Safety Commission are codified at 16 CFR 1600 (Subchapter D). The regulations prescribe procedures for developing flammability standards as well as specific flammability standards themselves.

The procedural rules adopt the criteria included in the FFA without further elaboration. Thus, the Commission must find that a flammability standard "may be needed to protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage." (16 CFR 1607.6) The other statutory criteria are similarly included in the regulations. The rules include no definition of "unreasonable risk."

STANDARDS

Flammability standards are defined for several classes of fabrics including clothing textiles (16 CFR 1610), vinyl plastic film (16 CFR 1611), children's sleepware (16 CFR 1615, 1616), carpets and rugs (16 CFR 1630, 1631), and mattresses and mattress pads (16 CFR 1632). These regulations essentially prescribe testing methods and procedures for flammability determinations, along with labeling, record-keeping, and other requirements. The regulations do not designate chemical substances which may not be incorporated in classes of fabrics or which must be limited as additives. Therefore, no further consideration of these regulations is required.

THE CONSUMER PRODUCT SAFETY ACT -- REGULATORY REVIEW

INTRODUCTION

Under the Consumer Product Safety Act, CPSC regulates consumer products containing hazardous substances if the products present an unreasonable risk of injury. In the past, unreasonable risks associated with consumer products have been brought to CPSC's attention via petitions submitted by interested citizens or organizations. Several of these petitions involved chemical substances; the remainder concerned consumer products which presented possible safety hazards unrelated to chemical substances. CPSC took regulatory action on the following substance-related petitions:

- petition to ban consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos;
- petition to ban paint and similar surface-coating materials for consumer use that contain lead or lead compounds;
- petition to require labeling of self-pressurized consumer products containing chlorofluorocarbons; and
- petition to require a standard for certain insulation that releases formaldehyde gas.

CPSC action on these products are discussed separately following a review of CPSA's regulatory provisions for designating hazardous substances.

Unlike the Federal Hazardous Substances Act which was transferred to CPSC in 1972, the Consumer Product Safety Act has been under CPSC's jurisdiction since its enactment. Thus, an analysis of CPSA regulations provides an opportunity to investigate how an independent regulatory commission interprets the Act within the context of setting safety standards or banning hazardous products. It is important to note that because CPSC regulates consumer products as defined in the statutes, it is not the Commission's responsibility to designate chemicals per se for regulation. However, CPSC may take, and has taken, CPSA action on products that contain chemical substances.

REGULATORY CRITERIA

According to the Consumer Product Safety Act Regulations (16 CFR 1110.11), CPSC bases its decision on whether or not a consumer product presents an unreasonable risk of injury on the following factors:

(1) Frequency and severity of injuries associated with a consumer product.

(2) Causality of injuries.

(3) Potential for a consumer product to cause chronic illness and injuries which do not become evident until some time after use or exposure to the product.

(4) Nature of the risk or injury in terms of its foreseeability by the consumer.

(5) Special vulnerability of children, elderly, and handicapped consumers to the risk of injury presented.

(6) Probability of injury to the consumer, taking into consideration such things as the number of units in use, frequency of use, and likelihood of exposure to the identified risk of injury during typical use.

(7) Any additional criteria which would lead the Commission to treat a petition as high priority matter.

If the Commission finds that a consumer product presents an unreasonable risk of injury, it may develop standards designed to reduce or eliminate the risk or it may declare the product to be a "banned hazardous product" based on "a finding that the product will be distributed in commerce and that it presents an unreasonable risk of injury for which no feasible consumer product safety standard under the CPSA would adequately protect the public" (16 CFR 1110.4). The CPSA regulations do not provide explicit criteria for designating chemical substances as "toxic", "hazardous", or otherwise subject to regulation.

The major criterion for designating a consumer product as hazardous is that a product presents an unreasonable risk of injury.

The factors considered by the CPSC in showing that an unreasonable risk exists come directly from the regulations (16 CFR 1110.11). In cases involving hazardous products, CPSC uses this regulation as a checklist to justify its rulemaking efforts. Much emphasis is placed upon describing the frequency and severity of injuries associated with a consumer product and upon the likelihood of exposure.

To support its findings that a product presents an unreasonable risk, CPSC has used (in addition to other evidence) epidemiological studies as well as animal bioassay data. Usually, the results of the studies have been summarized for CPSC in petitions requesting regulatory action. CPSC relies a great deal upon petitioners to convince the Commission that unreasonable risks are actually present instead of conducting its own research to substantiate the claim. CPSC has not tended to initiate action on its own; products have come up for consideration primarily through petitions and consumer complaints.

Exhibit 5-7 presents for each substance-related action the types of information used to support designation, including other agency regulations or data.

EXHIBIT 5-7

DESIGNATION CRITERIA FOR HAZARDOUS SUBSTANCES UNDER CPSA

	Asbestos	Lead	Chloro-Fluorocarbons	Urea-Formaldehyde
A. Designation as Hazardous				
1. Health Effects Data				
Epidemiological data (occupational)	X			X
Epidemiological data (non-occupational)	X	X		X
Animal bioassay data				X
Other agency regulations or data	X	X	X	X
Cumulative effects data	X			
Information contained in petitions	X	X	X	X
Other scientific studies			X	
Consumer complaints				X
2. Exposure Considerations				
Significant Exposure	X	X		X
Widespread environmental pollutant	X		X	
B. Designation as Banned Hazardous				
1. No known safe threshold	X	X		X
2. No adverse economic effects as a result of ban	X	X		
3. No adverse environmental effects as result of ban	X	X		X
4. Availability of substitutes	X	X		X
5. No feasible alternative that would adequately protect public from unreasonable risk of injury	X	X		X
C. Designation for Labeling Requirement				
1. Economic Considerations			X	NO FINAL RULE YET
2. Environmental Considerations			X	

CPSC may declare a product to be a "banned hazardous product" when no "feasible" safety standard would adequately protect the public.

Once a product meets the unreasonable risk criteria, CPSC may promulgate a regulation to ban the product if "no feasible consumer product safety standard under the CPSA would adequately protect the public" (16 CFR 1110.4). In its proceedings to ban consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos and lead-based paint and products containing lead-based paint, CPSC acted in accordance with section 9(c)(1). Section 9(c)(1) requires CPSC to consider the degree and nature of the risk involved, the approximate number of products to be affected, the public need for the product, and the economic effects of the rule. Exhibit 5-7, part B, lists the factors considered by CPSC in banning the particular asbestos and lead products.

In the asbestos case, CPSC also took into account the fact that no known safe threshold of asbestos exposure has yet to be determined.

CPSC may promulgate labeling regulations for products.

In order to reduce or eliminate the unreasonable risks of injury associated wth a consumer product, CPSC may promulgate rules to require cautionary labels on the products. Sections 7 and 9 require the CPSC to consider the degree and nature of the risk involved, the number of products expected to be affected, the public need for the product, and the economic effects of the rule. Alternately, the CPSC may promulgate rules requiring any manufacturer of consumer products to give notice of "performance and technical data" related to safety to both purchasers and prospective purchasers. This Section 27(e) authority is broader than the labeling authority included in Sections 7 and 9, because no findings of unreasonable risk, for example, are required. Section 27(e) authority was used as the basis for issuing warning requirements for chloroflurocarbons as well as the proposed labeling rules for urea-formaldehyde foam insulation.

When confronted with a hazardous product, CPSC can choose between regulating under the FHSA or the CPSA.

In a separate section on designating hazardous substances under the Federal Hazardous Substances Act, we noted that CPSC has tended to promulgate rules under the Consumer Product Safety Act instead of the FHSA. This option presents a potential source of confusion as well as a source of duplicative efforts.

In 1972, the Food and Drug Administration declared paint and other similar surface-coating materials intended, or packaged in a form suitable, for use in and around the household to be a banned hazardous product under the Federal Hazardous Substances Act. The regulation pertained to products in which the lead content was in excess of 0.6 percent of the total weight of the contained solids if the product entered interstate commerce after December 31, 1973. Up until that date, but after December 31, 1972, the regulated lead content level was 0.5 percent.

As detailed in this section CPSC issued a proposal under the CPSA to ban paint or other surface coating materials containing lead compounds in which the lead content is in excess of 0.06 percent by weight of the total nonvolatile content of the paint or the weight of the dried paint film (41 FR 33637, August 10, 1976). CPSC subsequently revoked the FHSA regulations concerning lead-based paint for products manufactured after February 27, 1978 (16 CFR 1500.17(6)(iii)). The resulting CPSA regulations are presumably more comprehensive than the FHSA regulations. Nevertheless, cases of this type may serve as striking examples of duplicative efforts in terms of reviewing evidence and engaging in the entire regulatory process again.

REGULATED SUBSTANCES

As of January 1, 1981, there are twelve final or proposed safety regulations under the CPSA (16 CFR 1201 to 1404); five of these regulations deal with products containing hazardous chemical substances. These five regulations involve four substances: asbestos, lead, chlorofluorocarbons, and urea-formaldehyde foam insulation. These regulations are reviewed next.

CPSC ACTION ON ASBESTOS

Between July 1976 and April 1977, CPSC received three petitions calling for regulatory action on certain products containing asbestos under the Federal Hazardous Substances Act (see Exhibit 5-8, Regulatory Chronology). Prior to issuing a proposal on the matter, CPSC determined that it was in the public interest to regulate these products under the CPSA rather than under the FHSA even though general-use garments containing asbestos had been banned under the FHSA (16 CFR 1500.17, 42 FR 63354). CPSC adopted this strategy mainly because the FHSA rulemaking process (governed by Section 710(e) of the Federal Food, Drug, and Cosmetic Act) would have involved lengthy hearings and unnecessary delays in promulgating a regulation. Although Section 9(a)(2) of the CPSA requires the Commission to provide an opportunity for oral presentation or comments before issuing a rule, the oral presentation is informal and nonadversarial, and is less likely to involve extensive delays. Another reason why CPSC opted for regulating the asbestos products under the CPSA instead of the FHSA is because the CPSA provides for civil penalties which might serve as an added incentive to comply with a rule.

Defining the Products

The regulations define asbestos as "a group of mineral fibers composed of hydrated silicates, oxygen, hydrogen, and other elements such as sodium, iron, magnesium, and calcium in diverse combinations and are: Amosite, chrysotile, crocidolite, anthrophyllite asbestos, anctinolite asbestos, and tremolite asbestos." Free-form asbestos is "that which is not bound, or otherwise locked-in to a product by resins or other bonding agents, or which can readily become airborne with any reasonably foreseeable use." (16 CFR 1304.3).

CPSC declared the following products containing free-form asbestos to be banned hazardous products under the CPSA: consumer patching compounds used to join or repair interior walls and ceilings, and artificial emberizing materials used in fireplaces to simulate live embers and ash (16 CFR 1304 and 1305).

Criteria Used to Designate Asbestos Products as Hazardous

In order to designate a product as hazardous, CPSC must determine that the product presents an unreasonable risk of injury. The risks associated with consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos are generally based upon the seriousness of health effects and the probability of incurring these health effects. These variables in turn are a function of other factors such as quantity, concentrations, and exposure.

Potential health effects arise because the asbestos in consumer patching compounds and artificial emberizing materials are capable of becoming airborne and thus respirable. Mixing of consumer patching compounds prior to application, sanding of the product after it is dried, and cleanup after application release asbestos fibers that can be inhaled. Asbestos fibers in embers and ash can be moved about the household by ordinary air currents.

Substantial evidence has indicated that the inhalation of asbestos fibers is associated with the risk of cancer. Specifically, the most common diseases linked to asbestos exposure are asbestosis, bronchogenic carcinoma, mesothelioma, and cancer of the stomach, colon, and rectum. These diseases underscore the seriousness of potential health effects from exposure to free-form asbestos.

The problem is compounded when exposure is taken into consideration. It has long been recognized that continuous and high levels of occupational exposure to asbestos could lead to disease. More recent data indicate that even low levels of exposure to asbestos, as in non-occupational settings, or brief or intermittent exposures to higher levels, can also lead to cancer. The only known study of consumer exposure to asbestos in spackling and other patching compounds indicated that product users and other household members were exposed to significant concentrations of asbestos. The presence in the household of persons, such as children, who may be particularly vulnerable to carcinogens would enhance the risk of asbestos exposure.

CPSC reviewed information contained in numerous studies (42 FR 38789, July 29, 1977, provides a complete list of references) before concluding that the seriousness of the injury and the potential for consumer exposure balanced against the costs of regulatory action supported a finding of unreasonable risk of injury. Based on this determination, CPSC treated consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos as banned hazardous products.

Criteria Used to Designate Asbestos Products as Banned Hazardous Products

A second, although not necessarily discrete, consideration for CPSC in designating products as banned hazardous products is whether or not any feasible standard under the CPSA can adequately protect the public from an unreasonable risk of injury. As CPSC reviewed the available information on asbestos risks, it discovered some uncertainties about the health effects of asbestos. For example, minimal exposure levels required to cause disease are not known. Furthermore, the actual risk of adverse health effects may be understated as malignancies can arise twenty years or more after exposure and many more cases of illness may still arise.

Because there is no known threshold level below which exposure to respirable free-form asbestos would be considered safe, CPSC concluded that no feasible standard under CPSA could adequately protect the public from risks and that a ban on consumer patching compounds and artificial emberizing materials containing respirable free-form asbestos would be necessary.

EXHIBIT 5-8

ASBESTOS PRODUCTS
REGULATORY CHRONOLOGY

7-15-76	Natural Resources Defense Council and Consumers Union petitioned CPSC under FHSA	
2-9-77	Public Citizens Health Research Group petitioned CPSC under FHSA	
4-15-77	Private consumer and Environmental Defense Fund joined in petitioning CPSC	
8-29-77	Proposed to ban respirable free-form asbestos in certain consumer patching compounds and artificial emberizing materials	42 FR 38783
12-15-77	CPSC issued final rule to ban certain products containing respirable free-form asbestos	42 FR 63354

CPSC ACTION ON LEAD PAINT

CPSC recently declared paint and other consumer products containing more than a safe level of lead to be banned hazardous products. CPSC's involvement with lead-based paint and other articles began with a 1973 Lead-Based Paint Poisoning Prevention Act (LBPPPA) directive to the Chairman of CPSC to ascertain a safe level of lead in residential paint products. Based on animal studies conducted for the Commission, CPSC found a 0.5 percent level of lead in paint to be safe. This level was then incorporated in regulations concerning lead-based paint, including CPSC's Federal Hazardous Substances Act regulations.

In 1976, an amendment to the LBPPPA directed CPSC to determine whether a level of lead in paint exceeding 0.06 percent, but not over 0.5 percent, was safe. Because CPSC was unable to determine that paint containing over 0.06% lead was safe, paint containing more than 0.06 percent lead became the basis for CPSC regulations.

On August 10, 1976, CPSC proposed to ban lead-based paint and other articles containing lead-based paint that fell under the jursidiction of the Consumer Product Safety Act (43 FR 33637). (See Exhibit 5-9, Regulatory Chronology.) The proposal pertained to consumer products containing more than the safe level of lead as determined in the LBPPPA proceedings. CPSC issued a final rule declaring these products to be banned hazardous products on September 1, 1977 (42 FR 44193).

Defining the Products

The ban applies to "paint or other similar surface coating materials containing lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 0.06 percent by weight of the total nonvolatile content of the paint or the weight of the dried paint film" (16 CFR 1303.2).

Other products declared as banned hazardous products are:

(1) Toys and other articles intended for use by children that bear lead-containing paint, and

(2) Furniture articles (except for metal furniture) for consumer use that bear lead-containing paint.

Criteria Used to Designate Lead-Based Paint Products as Hazardous

CPSC used the unreasonable risk of injury criterion to designate products containing lead-based paint as hazardous. Lead-based paint is the main source of lead poisoning in children (42 FR 44198), especially those with pica (a condition involving the repetitive ingestion of nonfood substances), who sometimes eat lead-containing paint or peelings from toys or furniture. The effects of such poisoning include hyperactivity, slowed learning ability, withdrawal, blindness, and even death.

In issuing the final rule to ban the lead-containing products, CPSC noted that the seriousness of the lead poisoning problem was well documented in a National Academy of Sciences report.

Criteria Used to Designate Lead-Based Paint Products as Banned Hazardous Products

CPSC based its decision to designate the products containing lead-based paint as banned hazardous products on the lack of any feasible safety standard that would adequately protect the public from unreasonable risks associated with paint containing more than 0.06 percent lead. CPSC stated that it was not aware of a technologically feasible procedure for detoxifying a hazardous quantity of lead when present in paint (42 FR 44199).

In banning paint and the articles containing paint with more than 0.06 percent lead, CPSC also considered economic factors such as the availability of substitutes and whether or not the ban's impact on the utility, cost, and availability of paints, etc., would outweigh the need to protect the public. See 16 CFR 1105.9(e).

EXHIBIT 5-9

LEAD-BASED PAINT REGULATORY CHRONOLOGY

2-24-75	Consumers Union petitioned CPSC	
8-10-76	CPSC proposed to ban paint and other articles under its jurisdiction that contain more than a safe level of lead	41 FR 33637
12-16-76	CPSC held earings on issue	42 FR 9404
9-1-77	CPSC issued final rule to establish lead containing paint and certain consumer products bearing lead-containing paint as banned hazardous products	42 FR 44193

CPSC ACTION ON CHLOROFLUOROCARBONS

CPSC's involvement with chlorofluorocarbons (CFC) began with a 1974 petition from the Natural Resources Defense Council that requested a ban on all aerosol products containing certain CFC compounds (see Exhibit 5-10, Regulatory Chronology). The petition alleged that the release of these compounds into the atmosphere caused depletion of the ozone layer and could ultimately lead to adverse health efects. CPSC denied the petition because of a lack of sufficient information.

In 1975 and 1976, CPSC received additional petitions related to CFC propellants. In November 1976, CPSC preliminarily found that aerosol products containing CFC propellants presented an unreasonable risk of injury. The finding eventually led CPSC to propose a rule to regulate CFCs in consumer products (42 FR 21807).

Initially, CPSC had intended to propose that the products be designated as banned hazardous products, however the Environmental Protection Agency's authority under TSCA to regulate non-essential uses of certain CFC propellants altered this strategy. An EPA proposed ban on the products would have rendered CPSC action unnecessary. Although CPSC decided against a ban under Section 8 of CPSA, it found that some regulatory action on the products was desirable in the interim prior to EPA action. Thus, CPSC issued a final rule requiring warning labels on aerosol products containing CFC propellants in August 1977 (42 FR 42780).

Defining the Product

For the purposes of the regulation (16 CFR 1401), chlorofluorocarbon means "any fully halogenated chlorofluoroalkane" and propellant means "a liquefied or compressed gas in a container, where a purpose of the liquefied or compressed gas is to expel material from the container." The labeling requirement applies to "self-pressurized products containing fully halogenated chlorofluorocarbons."

Criteria Used to Designate CFC Products for Regulation

CPSC based its finding that aerosol products using CFC propellants presented an unreasonable risk of injury on information contained in petitions and scientific reports. These petitions and reports indicated that the products in question may indirectly pose serious adverse health effects. In particular, CFCs released into the atmosphere may cause depletion of the stratospheric ozone which is important in protecting the earth from the sun's shortwave ultraviolet rays. This depletion in turn could lead to a significant increase in skin cancer. Another possible consequence of ozone depletion is climatic change.

Because CFCs had been widely used as propellants in a number of consumer aerosol products and because use of the products resulted in the release of CFCs into the atmosphere, CPSC determined that regulatory action was necessary to protect the public from the unreasonable risk of injury associated with the products.

EXHIBIT 5-10

CHLOROFLUOROCARBONS REGULATORY CHRONOLOGY

11-20-74	Natural Resources Defense Council petitioned CPSC
8-20-75	CPSC denied petition on the grounds that sufficient information was lacking
12-23-75 to 8-26-76	CPSC received more petitions and information

EXHIBIT 5-10

CHLOROFLUOROCARBONS REGULATORY CHRONOLOGY
(Continued)

10-14-76	Chemical Specialties Manufacturers Association, Inc., petitioned CPSC to issue a labeling rule for aerosol products with certain CFC propellants	
4-29-77	CPSC proposed a rule to regulate CFCs in certain consumer products	42 FR 21807
8-24-77	CPSC issued final rule	42 FR 42780

CPSC PROPOSED ACTION ON UREA-FORMALDEHYDE FOAM INSULATION

CPSC's involvement with urea-formaldehyde (U.F.) foam insulation provides an interesting example of regulatory response in the wake of numerous consumer complaints about a product. In the fall of 1976, CPSC received a petition about the possible adverse health effects associated with the release of formaldehyde gas from U.F. foam insulation (see Exhibit 5-11, Regulatory Chronology). It was not until spring 1979 when CPSC had received 195 incidents of health problems that it began to undertake further investigations into the matter. By March 1980 CPSC reportedly received over 1,000 consumer complaints about U.F. foam insulation, and in June 1980, it issued a proposal to regulate the sale of the product to consumers (45 FR 39434) by requiring manufacturers to include information on the sales contract concerning the risk of acute illness caused by the release of formaldehyde gas. In February 1981, after receiving the report of a federal panel established to assess the risk of chronic injury associated with formaldehyde, the CPSC proposed a ban of the product.

Defining the Product

The proposed definition of the product to be regulated is as follows:

> "Urea-formaldehyde (U.F.) foam insulation", also referred to as formaldehyde-based foam insulation, or foamed-in-place insulation, is a cellular plastic thermal insulation material which contains as a component chemical formaldehyde, formaldehyde derivatives, or any other chemical from which formaldehyde can be released. The produce is manufactured at the jobsite by mixing two liquid chemicals -- urea-formaldehyde based (or urea-based) resin and a foaming agent-- and, generally, pressurized air, through a foaming equipment system. The resultant mix has a shaving cream-like consistency and is usually pumped through relatively small holes into the walls of standing structures. After it is in the wall, the product cures and becomes firm or self-supporting.

Criteria for Designating U.F. Foam Insulation for Regulation

The basic criterion CPSC used in designating U.F. foam insulation as a hazardous product was the unreasonable risk of injury caused by the release of formaldehyde gas. In addition to consumer complaints, CPSC based its proposal to regulate U.F. foam insulation on various medical and scientific reports. One report, a National Academy of Sciences study for CPSC, involved an assessment of whether there is a tolerable level of formaldehyde in the air of homes. Another study, conducted by the Chemical Industry Institute for Toxicology, reported preliminary test results showing that formaldehyde causes cancer in some laboratory animals. CPSC considered a report prepared by a federal panel evaluating the chronic toxicity of formaldehyde. The panel concluded that formaldehyde should be presumed to pose a carcinogenic risk to humans. CPSC also took into account actions taken by state and other federal agencies with respect to U.F. foam insulation.

From these sources CPSC learned that formaldehyde released from insulation can cause serious illness in humans. Among the more common short-term reactions are eye, nose, and throat irritations, coughing, shortness of breath, skin irritation, nausea, headaches, and dizziness. The formaldehyde release can lead to more serious reactions for persons with respiratory problems or allergies.

CPSC followed up on some of the consumer complaints with in-depth investigations to document the types of reactions caused by exposure to formaldehyde gas and also to measure the amount of formaldehyde gas released into the homes. In air sample measurements, CPSC investigators utilized the National Institute for Occupational Safety and Health procedure for air collection and laboratory analysis.

Another criterion CPSC used in designating the foam insulation as a hazardous product was the amount and duration of exposure to formaldehyde gas. A University of Iowa quantitative study on the release of the gas from U.F. foam insulation and technical data presented by an expert at the University of Washington supported the following (45 FR 39436):

(1) U.F. foam insulation will release a measurable amount of formaldehyde after it is manufactured; and

(2) The insulation may release formaldehyde gas into the home for an indefinite period of time after installation.

EXHIBIT 5-11

U.F. FOAM INSULATION REGULATORY CHRONOLOGY

10-20-76	Metropolitan Denver District Attorney's Consumer Office petitioned CPSC to develop safety standards for certain types of home insulation	
8-22-77	CPSC held public hearing to discuss issues raised by petition	
6-10-78	CPSC published proposed rule to notify purchasers of U.F. foam insulation of the possible adverse health effects associated with the release of formaldehyde gas	45 FR 39434
12-3-79	CPSC announced it would hold public hearings to obtain more information on the safety of formaldehyde gas released from U.F. foam insulation	44 FR 69578

NUCLEAR REGULATORY COMMISSION

The following reviews discuss statutes and regulations administered by NRC. The statutory review discusses the Atomic Energy Act of 1954, the regulatory review covers regulations promulgated under the Act.

The legal review and regulatory analyses that follow do not necessarily represent the official position of NRC. Moreover, this material has not been officially endorsed by the EPA as its understanding of NRC's authority. The contractor, ICF Incorporated, and its subcontractor, Lawrence W. Bierlein, P.C., are solely responsible for all analyses and interpretations.

ATOMIC ENERGY ACT--STATUTORY REVIEW[1]

The Atomic Energy Act is directed to the safe development of nuclear power and the uses of atomic energy. The scope of activity conducted under the statute is somewhat limitd by definitions of the materials to be regulated. Although discretion to regulate these materials is broad, the authority to designate materials within the definitions is cumbersome and inflexible.

Section 2012 contains Congressional findings, including (1) "The processing and utilization of source, byproduct, and special nuclear material must be regulated in the national interest and in order to provide for the common defense and security and to protect the health and safety of the public," and (2) "Source and special nuclear material production facilities, and utilization facilities are affected with the public interest, and regulation by the United States of the production and utilization of atomic energy and of the facilities used in connection therewith is necessary in the national interest to assure the common defense and security and to protect the health and safety of the public."

The term "atomic energy" is the statute means all forms of energy released in the course of nuclear fission or nuclear transformation. "Byproduct material," "source material," and "special nuclear material" are defined in the statute as follows:

The term "byproduct material" means (1) any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material, and (2) the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

The term "source material" means (1) uranium, thorium, or any other material which is determined by the Commission pursuant to the provisions of Section 61 (42 USC 2091) to be a source material; or (2) ores containing one or more of the foregoing materials, in such concentration as the Commission may be regulation determine from time to time.

The term "special nuclear material" means (1) plutonium, uranium enriches in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of Section 51 (42 USC 2071), determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing, but does not include source material.

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[1] 42 USC 2011 *et seq*.

Section 2091, granting the Commission authority to determine what constitutes source material, requires a finding that the material is essential to the production of special nuclear material and that the determination is in the interest of the common defense and security, and that the President has agreed in writing. Section 2071 says that, before making the determination that something is special nuclear material, the Commission must find that the material is capable of releasing substantial quantities of atomic energy and must find that such a determination is in the interest of the common defense and security and that the President agrees. These determinations in turn must be submitted to Congress before they may become effective.

The term "nuclear incident" means any occurrence, including an extraordinary nuclear occurrence, within the United States causing, within or outside the United States, bodily injury, sickness, disease, or death, or loss of or damage to property, or loss of use of property, arising out of or resulting from the radioactive, toxic, explosive, or other hazardous properties of source, special nuclear, or byproduct material.

Within the Nuclear Regulatory Commission, the Director of Nuclear Reactor Regulation reviews the safety and safeguards of all facilities, materials, and activities under the Atomic Energy Act, including, but not limited to, monitoring, testing and recommending upgrading of systems designed to prevent substantial health or safety hazards, and evaluation methods of transporting special nuclear and other nuclear materials and of transporting and storing high-level radioactive wastes to prevent radiation hazards to employees and the general public.

The Office of Nuclear Material Safety and Safeguards has a similar role with an emphasis on safeguards against threats, thefts, and sabotage of licensed facilities and materials.

NUCLEAR REGULATORY COMMISSION--REGULATORY REVIEW[2]

The regulations of the Nuclear Regulatory Commission are issued under the authority of the Atomic Energy Act of 1954, 42 USC Section 2011. The regulations are published in 10 CFR Parts 0-170.

Part 20 of 10 CFR prescribes standards for protection against radiation. Section 20.3 within this Part offers several definitions pertinent to the designation of radioactive materials. Radioactive material is defined as, "any such material whether or not subject to licensing control by the (Nuclear Regulatory) Commission". Radiation is defined in this section as "any or all of the following: alpha rays, beta rays, gamma rays, X-rays, neutrons, high-speed electrons, high-speed protons, and other atomic particles; but not sound or radio waves, or visible, infrared, or ultraviolet light".

Part 20 prescribes standards in terms of "permissible dose levels and concentrations" of radiation exposure for workers and the public. Various precautionary procedures are prescribed. The basic controls of the Nuclear Regulatory Commission are carried out through various licensing programs for source material, special nuclear material, and by-product material. These are regulated in Parts 40, 70 and 30, respectively of 10 CFR. Part 40 defines source material as, "(1) uranium or thorium, or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of: (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material".

Special nuclear material is defined in Section 70.4(m) as "(1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Commission, pursuant to the provisions of Section 51 of the Act, determines to be special nuclear material, but does not include source material; or (2) any material artificially enriched by any of the foregoing but does not include source material".

By-product material is defined in Section 30.4(d) as, "any radioactive material (ecept special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material". The same term is given a somewhat different definition in Section 40.4(a-1). There, by-product material is defined as, "the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed, primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by such solution extraction operations do not constitute 'by-product' material within this definition". It should be noted that the definition of by-product material in Section 40.4 is limited to the use of that term in Part 40, whereas the definition in Section 30.4 is for use in Part 30-35.

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[2] Prepared by Lawrence W. Bierlein, P.C., subcontractor to ICF Incorporated.

Whereas the definitions of basically regulated materials are virtually identical to definitions for these terms in the Atomic Energy Act, there is an exercise of discretion in application of regulatory requirements to these materials. In addition, there appears to be significant use of exemption authority to relieve certain defined materials from either certain regulations or all regulations.

Throughout the operative parts of the NRC regulations in 10 CFR, there are frequent references to exemptions and "specific exemptions". The exemp- tions include exemptions by rule for low-hazard materials or people governed under other regulations, or people who have only a peripheral contractual involvement in the handling of radioactive materials. Part 30.14, for example, is entitled "Unimportant Quantities of Source Material" and describes low-risk materials and exempts people handling those materials from various requirements, generally including exemption from licensing requirements. Throughout the regulations one also finds reference to specific exemptions. Part 30.11 reads that "The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the requirements of the regulation in this part as it determines or authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest". In its deliberations upon an application for exemption, the NRC must consider and "balance" the following factors: "(1) whether conduct of the proposed activities will give rise to a significant adverse impact on the environment and the nature and extent of such impact, if any; (2) whether redress of any adverse environmental impact or conduct of the proposed activities can reasonably be effected should such redress be necessary; (3) whether conduct of the proposed activities would foreclose subsequent adoption of alternatives; and (4) the effect of delay in conducting such activities on the public interest. During the period of any exemption granted pursuant to this paragraph, any activities conducted shall be carried out in such a manner as will minimize or reduce their environmental impact".

Exemption alternatives such as that just quoted appear in the following parts: 20.501, 21.7, 30.11, 34.51, 40.14, 50.12, 51.4, 55.7, 70.14, 71.6, 110.10(a), and 140.8.

As can be seen from the proliferation of exemption sections, in addition to exemptions by rule, the NRC's designation authority takes the form of non-designation of hazardous materials. In other words, the Atomic Energy Act of 1954 defines materials to be regulated, and this statutory rigidity is ameliorated by the exemption process through which specific people, materials and functions are relieved from the full impact of regulatory requirements, primarily licensing. Although the regulations do discuss the generic categories of concern, such as the concern for the public interest and the environment, these matters are not in any form quantified nor is the applicant for an exemption advised by the regulations of the details that will prevail in an exemption application.